

EXHIBIT 6



ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Todd M. Schneider (SBN 158253), Jason H. Kim (SBN 220279) Matthew S. Weiler (SBN 236052), Kyle G. Bates (SBN 299114) Schneider Wallace Cottrell Konecky LLP 2000 Powell Street, Suite 1400, Emeryville, California 94608 TELEPHONE NO.: 415-421-7100 FAX NO.: 415-421-7105 ATTORNEY FOR (Name): Health Care Service Corp.		22687409 FILED ALAMEDA COUNTY FEB 27 2020 CLERK OF THE SUPERIOR COURT By <i>[Signature]</i> Deputy	
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Alameda STREET ADDRESS: 1225 Fallon Street MAILING ADDRESS: 1225 Fallon Street CITY AND ZIP CODE: Oakland, California 94612 BRANCH NAME: Rene C. Davidson Courthouse			
CASE NAME: Health Care Service Corp. v. Mallinckrodt ARD, LLC, et al.			
CIVIL CASE COVER SHEET <input checked="" type="checkbox"/> Unlimited (Amount demanded exceeds \$25,000) <input type="checkbox"/> Limited (Amount demanded is \$25,000 or less)		Complex Case Designation <input type="checkbox"/> Counter <input type="checkbox"/> Joinder Filed with first appearance by defendant (Cal. Rules of Court, rule 3.402)	CASE NUMBER: <i>R920056354</i>
		JUDGE:	DEPT:

Items 1–6 below must be completed (see instructions on page 2).

1. Check **one** box below for the case type that best describes this case:

Auto Tort <input type="checkbox"/> Auto (22) <input type="checkbox"/> Uninsured motorist (46) Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort <input type="checkbox"/> Asbestos (04) <input type="checkbox"/> Product liability (24) <input type="checkbox"/> Medical malpractice (45) <input type="checkbox"/> Other PI/PD/WD (23) Non-PI/PD/WD (Other) Tort <input type="checkbox"/> Business tort/unfair business practice (07) <input type="checkbox"/> Civil rights (08) <input type="checkbox"/> Defamation (13) <input type="checkbox"/> Fraud (16) <input type="checkbox"/> Intellectual property (19) <input type="checkbox"/> Professional negligence (25) <input type="checkbox"/> Other non-PI/PD/WD tort (35) Employment <input type="checkbox"/> Wrongful termination (36) <input type="checkbox"/> Other employment (15)	Contract <input type="checkbox"/> Breach of contract/warranty (06) <input type="checkbox"/> Rule 3.740 collections (09) <input type="checkbox"/> Other collections (09) <input type="checkbox"/> Insurance coverage (18) <input type="checkbox"/> Other contract (37) Real Property <input type="checkbox"/> Eminent domain/Inverse condemnation (14) <input type="checkbox"/> Wrongful eviction (33) <input type="checkbox"/> Other real property (26) Unlawful Detainer <input type="checkbox"/> Commercial (31) <input type="checkbox"/> Residential (32) <input type="checkbox"/> Drugs (38) Judicial Review <input type="checkbox"/> Asset forfeiture (05) <input type="checkbox"/> Petition re: arbitration award (11) <input type="checkbox"/> Writ of mandate (02) <input type="checkbox"/> Other judicial review (39)	Provisionally Complex Civil Litigation (Cal. Rules of Court, rules 3.400–3.403) <input checked="" type="checkbox"/> Antitrust/Trade regulation (03) <input type="checkbox"/> Construction defect (10) <input type="checkbox"/> Mass tort (40) <input type="checkbox"/> Securities litigation (28) <input type="checkbox"/> Environmental/Toxic tort (30) <input type="checkbox"/> Insurance coverage claims arising from the above listed provisionally complex case types (41) Enforcement of Judgment <input type="checkbox"/> Enforcement of judgment (20) Miscellaneous Civil Complaint <input type="checkbox"/> RICO (27) <input type="checkbox"/> Other complaint (not specified above) (42) Miscellaneous Civil Petition <input type="checkbox"/> Partnership and corporate governance (21) <input type="checkbox"/> Other petition (not specified above) (43)
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2. This case ☒ is ☐ is not complex under rule 3.400 of the California Rules of Court. If the case is complex, mark the factors requiring exceptional judicial management:
- | | |
|--|---|
| a. <input type="checkbox"/> Large number of separately represented parties
b. <input checked="" type="checkbox"/> Extensive motion practice raising difficult or novel issues that will be time-consuming to resolve
c. <input checked="" type="checkbox"/> Substantial amount of documentary evidence | d. <input checked="" type="checkbox"/> Large number of witnesses
e. <input type="checkbox"/> Coordination with related actions pending in one or more courts in other counties, states, or countries, or in a federal court
f. <input type="checkbox"/> Substantial postjudgment judicial supervision |
|--|---|
3. Remedies sought (check all that apply): a. ☒ monetary b. ☒ nonmonetary; declaratory or injunctive relief c. ☒ punitive
4. Number of causes of action (specify):
5. This case ☐ is ☒ is not a class action suit.
6. If there are any known related cases, file and serve a notice of related case. (You may use form CM-015.)

Date: February 27, 2020
 Matthew S. Weiler, Esq.

(TYPE OR PRINT NAME)

(SIGNATURE OF PARTY OR ATTORNEY FOR PARTY)

NOTICE

- Plaintiff must file this cover sheet with the first paper filed in the action or proceeding (except small claims cases or cases filed under the Probate Code, Family Code, or Welfare and Institutions Code). (Cal. Rules of Court, rule 3.220.) Failure to file may result in sanctions.
- File this cover sheet in addition to any cover sheet required by local court rule.
- If this case is complex under rule 3.400 et seq. of the California Rules of Court, you must serve a copy of this cover sheet on all other parties to the action or proceeding.
- Unless this is a collections case under rule 3.740 or a complex case, this cover sheet will be used for statistical purposes only.

Page 1 of 2

INSTRUCTIONS ON HOW TO COMPLETE THE COVER SHEET

To Plaintiffs and Others Filing First Papers. If you are filing a first paper (for example, a complaint) in a civil case, you **must** complete and file, along with your first paper, the *Civil Case Cover Sheet* contained on page 1. This information will be used to compile statistics about the types and numbers of cases filed. You must complete items 1 through 6 on the sheet. In item 1, you must check **one** box for the case type that best describes the case. If the case fits both a general and a more specific type of case listed in item 1, check the more specific one. If the case has multiple causes of action, check the box that best indicates the **primary** cause of action. To assist you in completing the sheet, examples of the cases that belong under each case type in item 1 are provided below. A cover sheet must be filed only with your initial paper. Failure to file a cover sheet with the first paper filed in a civil case may subject a party, its counsel, or both to sanctions under rules 2.30 and 3.220 of the California Rules of Court.

To Parties in Rule 3.740 Collections Cases. A "collections case" under rule 3.740 is defined as an action for recovery of money owed in a sum stated to be certain that is not more than \$25,000, exclusive of interest and attorney's fees, arising from a transaction in which property, services, or money was acquired on credit. A collections case does not include an action seeking the following: (1) tort damages, (2) punitive damages, (3) recovery of real property, (4) recovery of personal property, or (5) a prejudgment writ of attachment. The identification of a case as a rule 3.740 collections case on this form means that it will be exempt from the general time-for-service requirements and case management rules, unless a defendant files a responsive pleading. A rule 3.740 collections case will be subject to the requirements for service and obtaining a judgment in rule 3.740.

To Parties in Complex Cases. In complex cases only, parties must also use the *Civil Case Cover Sheet* to designate whether the case is complex. If a plaintiff believes the case is complex under rule 3.400 of the California Rules of Court, this must be indicated by completing the appropriate boxes in items 1 and 2. If a plaintiff designates a case as complex, the cover sheet must be served with the complaint on all parties to the action. A defendant may file and serve no later than the time of its first appearance a joinder in the plaintiff's designation, a counter-designation that the case is not complex, or, if the plaintiff has made no designation, a designation that the case is complex.

CASE TYPES AND EXAMPLES**Auto Tort**

Auto (22)–Personal Injury/Property Damage/Wrongful Death
Uninsured Motorist (46) (*if the case involves an uninsured motorist claim subject to arbitration, check this item instead of Auto*)

Other PI/PD/WD (Personal Injury/Property Damage/Wrongful Death) Tort

Asbestos (04)
Asbestos Property Damage
Asbestos Personal Injury/Wrongful Death
Product Liability (*not asbestos or toxic/environmental*) (24)
Medical Malpractice (45)
Medical Malpractice–Physicians & Surgeons
Other Professional Health Care Malpractice
Other PI/PD/WD (23)
Premises Liability (e.g., slip and fall)
Intentional Bodily Injury/PD/WD (e.g., assault, vandalism)
Intentional Infliction of Emotional Distress
Negligent Infliction of Emotional Distress
Other PI/PD/WD

Non-PI/PD/WD (Other) Tort

Business Tort/Unfair Business Practice (07)
Civil Rights (e.g., discrimination, false arrest) (*not civil harassment*) (08)
Defamation (e.g., slander, libel) (13)
Fraud (16)
Intellectual Property (19)
Professional Negligence (25)
Legal Malpractice
Other Professional Malpractice (*not medical or legal*)
Other Non-PI/PD/WD Tort (35)

Employment

Wrongful Termination (36)
Other Employment (15)

Contract

Breach of Contract/Warranty (06)
Breach of Rental/Lease Contract (*not unlawful detainer or wrongful eviction*)
Contract/Warranty Breach–Seller Plaintiff (*not fraud or negligence*)
Negligent Breach of Contract/Warranty
Other Breach of Contract/Warranty
Collections (e.g., money owed, open book accounts) (09)
Collection Case–Seller Plaintiff
Other Promissory Note/Collections Case
Insurance Coverage (*not provisionally complex*) (18)
Auto Subrogation
Other Coverage
Other Contract (37)
Contractual Fraud
Other Contract Dispute

Real Property

Eminent Domain/Inverse Condemnation (14)
Wrongful Eviction (33)
Other Real Property (e.g., quiet title) (26)
Writ of Possession of Real Property
Mortgage Foreclosure
Quiet Title
Other Real Property (*not eminent domain, landlord/tenant, or foreclosure*)

Unlawful Detainer

Commercial (31)
Residential (32)
Drugs (38) (*if the case involves illegal drugs, check this item; otherwise, report as Commercial or Residential*)

Judicial Review

Asset Forfeiture (05)
Petition Re: Arbitration Award (11)
Writ of Mandate (02)
Writ–Administrative Mandamus
Writ–Mandamus on Limited Court Case Matter
Writ–Other Limited Court Case Review
Other Judicial Review (39)
Review of Health Officer Order
Notice of Appeal–Labor
Commissioner Appeals

Provisionally Complex Civil Litigation (Cal. Rules of Court Rules 3.400–3.403)

Antitrust/Trade Regulation (03)
Construction Defect (10)
Claims Involving Mass Tort (40)
Securities Litigation (28)
Environmental/Toxic Tort (30)
Insurance Coverage Claims (*arising from provisionally complex case type listed above*) (41)

Enforcement of Judgment

Enforcement of Judgment (20)
Abstract of Judgment (Out of County)
Confession of Judgment (*non-domestic relations*)
Sister State Judgment
Administrative Agency Award (*not unpaid taxes*)
Petition/Certification of Entry of Judgment on Unpaid Taxes
Other Enforcement of Judgment Case

Miscellaneous Civil Complaint

RICO (27)
Other Complaint (*not specified above*) (42)
Declaratory Relief Only
Injunctive Relief Only (*non-harassment*)
Mechanics Lien
Other Commercial Complaint Case (*non-tort/non-complex*)
Other Civil Complaint (*non-tort/non-complex*)

Miscellaneous Civil Petition

Partnership and Corporate Governance (21)
Other Petition (*not specified above*) (43)
Civil Harassment
Workplace Violence
Elder/Dependent Adult Abuse
Election Contest
Petition for Name Change
Petition for Relief From Late Claim
Other Civil Petition

F. ADDENDUM TO CIVIL CASE COVER SHEET

Short Title: Health Care Service Corp. v. Mallinckrodt ARD, LLC	Case Number:
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CIVIL CASE COVER SHEET ADDENDUM

**THIS FORM IS REQUIRED IN ALL NEW UNLIMITED CIVIL CASE FILINGS IN THE
SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA**

<input type="checkbox"/> Hayward Hall of Justice (447) <input checked="" type="checkbox"/> Oakland, Rene C. Davidson Alameda County Courthouse (446)		<input type="checkbox"/> Pleasanton, Gale-Schenone Hall of Justice (448)	
Civil Case Cover Sheet Category	Civil Case Cover Sheet Case Type	Alameda County Case Type (check only one)	
Auto Tort	Auto tort (22)	<input type="checkbox"/> 34 Auto tort (G) Is this an uninsured motorist case? <input type="checkbox"/> yes <input type="checkbox"/> no	
Other PI /PD / WD Tort	Asbestos (04)	<input type="checkbox"/> 75 Asbestos (D)	
	Product liability (24)	<input type="checkbox"/> 89 Product liability (<u>not</u> asbestos or toxic tort/environmental) (G)	
	Medical malpractice (45)	<input type="checkbox"/> 97 Medical malpractice (G)	
	Other PI/PD/WD tort (23)	<input type="checkbox"/> 33 Other PI/PD/WD tort (G)	
Non - PI /PD / WD Tort	Bus tort / unfair bus. practice (07)	<input type="checkbox"/> 79 Bus tort / unfair bus. practice (G)	
	Civil rights (08)	<input type="checkbox"/> 80 Civil rights (G)	
	Defamation (13)	<input type="checkbox"/> 84 Defamation (G)	
	Fraud (16)	<input type="checkbox"/> 24 Fraud (G)	
	Intellectual property (19)	<input type="checkbox"/> 87 Intellectual property (G)	
	Professional negligence (25)	<input type="checkbox"/> 59 Professional negligence - non-medical (G)	
	Other non-PI/PD/WD tort (35)	<input type="checkbox"/> 03 Other non-PI/PD/WD tort (G)	
Employment	Wrongful termination (36)	<input type="checkbox"/> 38 Wrongful termination (G)	
	Other employment (15)	<input type="checkbox"/> 85 Other employment (G)	
		<input type="checkbox"/> 53 Labor comm award confirmation	
		<input type="checkbox"/> 54 Notice of appeal - L.C.A.	
Contract	Breach contract / Wrnty (06)	<input type="checkbox"/> 04 Breach contract / Wrnty (G)	
	Collections (09)	<input type="checkbox"/> 81 Collections (G)	
	Insurance coverage (18)	<input type="checkbox"/> 86 Ins. coverage - non-complex (G)	
	Other contract (37)	<input type="checkbox"/> 98 Other contract (G)	
Real Property	Eminent domain / Inv Cdm (14)	<input type="checkbox"/> 18 Eminent domain / Inv Cdm (G)	
	Wrongful eviction (33)	<input type="checkbox"/> 17 Wrongful eviction (G)	
	Other real property (26)	<input type="checkbox"/> 36 Other real property (G)	
Unlawful Detainer	Commercial (31)	<input type="checkbox"/> 94 Unlawful Detainer - commercial	Is the deft. in possession of the property? <input type="checkbox"/> Yes <input type="checkbox"/> No
	Residential (32)	<input type="checkbox"/> 47 Unlawful Detainer - residential	
	Drugs (38)	<input type="checkbox"/> 21 Unlawful detainer - drugs	
Judicial Review	Asset forfeiture (05)	<input type="checkbox"/> 41 Asset forfeiture	
	Petition re: arbitration award (11)	<input type="checkbox"/> 62 Pet. re: arbitration award	
	Writ of Mandate (02)	<input type="checkbox"/> 49 Writ of mandate	
	Other judicial review (39)	Is this a CEQA action (Publ.Res.Code section 21000 et seq) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 64 Other judicial review	
Provisionally Complex	Antitrust / Trade regulation (03)	<input checked="" type="checkbox"/> 77 Antitrust / Trade regulation	
	Construction defect (10)	<input type="checkbox"/> 82 Construction defect	
	Claims involving mass tort (40)	<input type="checkbox"/> 78 Claims involving mass tort	
	Securities litigation (28)	<input type="checkbox"/> 91 Securities litigation	
	Toxic tort / Environmental (30)	<input type="checkbox"/> 93 Toxic tort / Environmental	
	Ins covrg from cmplx case type (41)	<input type="checkbox"/> 95 Ins covrg from complex case type	
Enforcement of Judgment	Enforcement of judgment (20)	<input type="checkbox"/> 19 Enforcement of judgment	
		<input type="checkbox"/> 08 Confession of judgment	
Misc Complaint	RICO (27)	<input type="checkbox"/> 90 RICO (G)	
	Partnership / Corp. governance (21)	<input type="checkbox"/> 88 Partnership / Corp. governance (G)	
	Other complaint (42)	<input type="checkbox"/> 68 All other complaints (G)	
Misc. Civil Petition	Other petition (43)	<input type="checkbox"/> 06 Change of name	
		<input type="checkbox"/> 69 Other petition	

Ex. 6

EXHIBIT 7

[Schneider Wallace Cottrell Konecky Wotkyns LLP Attn: Schneider, Todd M. 2000 Powell St. Suite 1400 Emeryville, CA 94608 _____	[Mallinckrodt ARD LLC]
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Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp <div style="text-align: right;">Plaintiff/Petitioner(s)</div> <div style="text-align: center;">VS.</div> Mallinckrodt ARD LLC <div style="text-align: right;">Defendant/Respondent(s)</div> <div style="text-align: center;">(Abbreviated Title)</div>	
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No. RG20056354

NOTICE OF HEARING

To each party or to the attorney(s) of record for each party herein:

Notice is hereby given that the above-entitled action has been set for:

Complex Determination Hearing
 Case Management Conference

You are hereby notified to appear at the following Court location on the date and time noted below:

Complex Determination Hearing:

DATE: 04/07/2020 **TIME:** 03:00 PM **DEPARTMENT:** 23
LOCATION: Administration Building, Fourth Floor
 1221 Oak Street, Oakland

Case Management Conference:

DATE: 05/19/2020 **TIME:** 03:00 PM **DEPARTMENT:** 23
LOCATION: Administration Building, Fourth Floor
 1221 Oak Street, Oakland

Pursuant to California Rules of Court, Rule 3.400 et seq. and Local Rule 3.250 (Unified Rules of the Superior Court, County of Alameda), the above-entitled matter is set for a Complex Litigation Determination Hearing and Initial Complex Case Management Conference.

Department 23 issues tentative rulings on DomainWeb (www.alameda.courts.ca.gov/domainweb). For parties lacking access to DomainWeb, the tentative ruling must be obtained from the clerk at (510) 267-6939. Please consult Rule 3.30(c) of the Unified Rules of the Superior Court, County of Alameda, concerning the tentative ruling procedures for Department 23.

Counsel or party requesting complex litigation designation is ordered to serve a copy of this notice on all parties omitted from this notice or brought into the action after this notice was mailed.

All counsel of record and any unrepresented parties are ordered to attend this Initial Complex Case Management Conference unless otherwise notified by the Court.

Failure to appear, comply with local rules or provide a Case Management Conference statement may result in sanctions. Case Management Statements may be filed by E-Delivery, by submitting directly to the E-Delivery Fax Number (510) 267-5732. No fee is charged for this service. For further information, go to **Direct Calendar Departments** at

<http://apps.alameda.courts.ca.gov/domainweb>.


All motions in this matter to be heard prior to Complex Litigation Determination Hearing must be scheduled for hearing in Department 23.

If the information contained in this notice requires change or clarification, please contact the courtroom clerk for Department 23 by e-mail at Dept.23@alameda.courts.ca.gov or by phone at (510) 267-6939.

TELEPHONIC COURT APPEARANCES at Case Management Conferences may be available by contacting CourtCall, an independent vendor, at least 3 business days prior to the scheduled conference. Parties can make arrangements by calling (888) 882-6878, or faxing a service request form to (888) 883-2946. This service is subject to charges by the vendor.

Dated: 03/03/2020

Chad Finke Executive Officer / Clerk of the Superior Court

By  ^{Digital}
Deputy Clerk

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice by placing copies in envelopes addressed as shown hereon and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 03/04/2020.

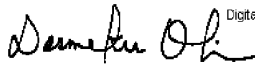
By  ^{Digital}
Deputy Clerk

EXHIBIT 8

POS-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Matthew Weiler, 236052 Schneider Wallace Cottrell Konecky LLP 2000 Powell Street, Suite 1400 Emeryville, CA 94608 TELEPHONE NO.: (510)740-2905 ATTORNEY FOR (Name): Plaintiff	FILED BY FAX^{LY} ALAMEDA COUNTY March 13, 2020 CLERK OF THE SUPERIOR COURT By Milagros Cortez, Deputy CASE NUMBER: RG20056354
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Superior Court of California, Alameda County 1225 Fallon Street, #109 Oakland, CA 94612-4293	
PLAINTIFF/PETITIONER: Health Care Service Corp. DEFENDANT/RESPONDENT: Mallinckrodt ARD LLC, et al.	CASE NUMBER: RG20056354
PROOF OF SERVICE OF SUMMONS	Ref. No. or File No.: Mallinckrodt - 102029

1. At the time of service I was a citizen of the United States, at least 18 years of age and not a party to this action. **BY FAX**
 2. I served copies of:
 Complaint, Civil Case Cover Sheet, Civil Case Cover Sheet Addendum, Summons on Complaint, Notice of Hearing, Alternative Dispute Resolution (ADR) Information Package

3. a. Party served: Mallinckrodt ARD LLC (f/k/a Mallinckrodt ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.)
 b. Person Served: Peter Cayetano-CT Corporation System - Person Authorized to Accept Service of Process

4. Address where the party was served: 818 West Seventh Street, Suite 930
 Los Angeles, CA 90017

5. I served the party
 a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on (date): 03/05/2020 (2) at (time): 2:30PM
 6. The "Notice to the Person Served" (on the summons) was completed as follows:

d. on behalf of:

Mallinckrodt ARD LLC (f/k/a Mallinckrodt ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.)
 under: Other: Limited Liability Company

7. **Person who served papers**

- a. Name: Jessica Brown
 b. Address: One Legal - P-000618-Sonoma
 1400 North McDowell Blvd, Ste 300
 Petaluma, CA 94954

c. Telephone number: 415-491-0606

d. The fee for service was: \$ 40.00

e I am:

- (3) registered California process server.
 (i) Employee or independent contractor.
 (ii) Registration No.: 2019217220
 (iii) County: Los Angeles

8. I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct.
 Date: 03/05/2020

Jessica Brown

(NAME OF PERSON WHO SERVED PAPERS)



(SIGNATURE)

EXHIBIT 9

POS-010

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): Matthew Weiler, 236052 Schneider Wallace Cottrell Konecky LLP 2000 Powell Street, Suite 1400 Emeryville, CA 94608 TELEPHONE NO.: (510)740-2905 ATTORNEY FOR (Name): Plaintiff	FILED BY FAX^{WLY} ALAMEDA COUNTY March 13, 2020 CLERK OF THE SUPERIOR COURT By Milagros Cortez, Deputy CASE NUMBER: RG20056354
SUPERIOR COURT OF CALIFORNIA, COUNTY OF Superior Court of California, Alameda County 1225 Fallon Street, #109 Oakland, CA 94612-4293	
PLAINTIFF/PETITIONER: Health Care Service Corp. DEFENDANT/RESPONDENT: Mallinckrodt ARD LLC, et al.	CASE NUMBER: RG20056354
PROOF OF SERVICE OF SUMMONS	Ref. No. or File No.: Mallinckrodt - 102029

1. At the time of service I was a citizen of the United States, at least 18 years of age and not a party to this action. **BY FAX**
 2. I served copies of:
 Complaint, Civil Case Cover Sheet, Civil Case Cover Sheet Addendum, Summons on Complaint, Notice of Hearing, Alternative Dispute Resolution (ADR) Information Package

3. a. Party served: Mallinckrodt PLC

b. Person Served: Peter Cayetano-CT Corporation System - Person Authorized to Accept Service of Process

4. Address where the party was served: 818 West Seventh Street, Suite 930
 Los Angeles, CA 90017

5. I served the party

a. **by personal service.** I personally delivered the documents listed in item 2 to the party or person authorized to receive service of process for the party (1) on (date): 03/05/2020 (2) at (time): 2:30PM

6. The "Notice to the Person Served" (on the summons) was completed as follows:

d. on behalf of:

Mallinckrodt PLC
 under: CCP 416.10 (corporation)

7. **Person who served papers**

a. Name: Jessica Brown

b. Address: One Legal - P-000618-Sonoma
 1400 North McDowell Blvd, Ste 300
 Petaluma, CA 94954

c. Telephone number: 415-491-0606

d. The fee for service was: \$ 40.00

e I am:

- (3) registered California process server.
 - (i) Employee or independent contractor.
 - (ii) Registration No.: 2019217220
 - (iii) County: Los Angeles

8. I declare under penalty of perjury under the laws of the United States of America and the State of California that the foregoing is true and correct.
 Date: 03/05/2020

Jessica Brown

(NAME OF PERSON WHO SERVED PAPERS)



(SIGNATURE)

EXHIBIT 10

[Schneider Wallace Cottrell Konecky Wotkyns LLP Attn: Schneider, Todd M. 2000 Powell St. Suite 1400 Emeryville, CA 94608 _____	[Mallinckrodt ARD LLC]
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Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp <div style="text-align: right;">Plaintiff/Petitioner(s)</div> VS. Mallinckrodt ARD LLC <div style="text-align: right;">Defendant/Respondent(s) (Abbreviated Title)</div>	No. <u>RG20056354</u> NOTICE OF HEARING (AMENDED) Complex Determination Hearing on 04/21/2020 has been vacated and rescheduled.
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To each party or to the attorney(s) of record for each party herein:

Notice is hereby given that the above-entitled action has been set for:

Complex Determination Hearing

You are hereby notified to appear at the following Court location on the date and time noted below:

Complex Determination Hearing:

DATE: 05/05/2020 TIME: 03:00 PM DEPARTMENT: 23

LOCATION: Administration Building, Fourth Floor
 1221 Oak Street, Oakland

Pursuant to California Rules of Court, Rule 3.400 et seq. and Local Rule 3.250 (Unified Rules of the Superior Court, County of Alameda), the above-entitled matter is set for a Complex Litigation Determination Hearing and Initial Complex Case Management Conference.

Department 23 issues tentative rulings on DomainWeb (www.alameda.courts.ca.gov/domainweb). For parties lacking access to DomainWeb, the tentative ruling must be obtained from the clerk at (510) 267-6939. Please consult Rule 3.30(c) of the Unified Rules of the Superior Court, County of Alameda, concerning the tentative ruling procedures for Department 23.

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All motions in this matter to be heard prior to Complex Litigation Determination Hearing must be scheduled for hearing in Department 23.

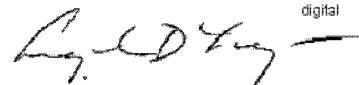
If the information contained in this notice requires change or clarification, please contact the courtroom clerk for Department 23 by e-mail at Dept.23@alameda.courts.ca.gov or by phone at (510) 267-6939.

TELEPHONIC COURT APPEARANCES at Case Management Conferences may be available by contacting CourtCall, an independent vendor, at least 3 business days prior to the scheduled conference. Parties can make arrangements by calling (888) 882-6878, or faxing a service request form to (888) 883-2946. This service is subject to charges by the vendor.

Dated: 04/20/2020

Chad Finke Executive Officer / Clerk of the Superior Court

By

 digital

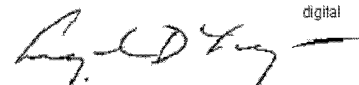
Deputy Clerk

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice by placing copies in envelopes addressed as shown hereon and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 04/20/2020.

By

 digital

Deputy Clerk

EXHIBIT 11

**ENDORSED
FILED
ALAMEDA COUNTY**

APR 30 2020

CLERK OF THE SUPERIOR COURT
By *C. Collins* Deputy

ARNOLD & PORTER KAYE SCHOLER LLP

Matthew M. Wolf (*PHV* to be filed)

Laura S. Shores (*PHV* to be filed)

Sonia Kuester Pfaffenroth (SBN 223984)

Michael B. Bernstein (*PHV* to be filed)

Adam M. Pergament (SBN 267557)

601 Massachusetts Avenue, N.W.

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777 South Figueroa Street, 44th Floor

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Attorneys for Defendant

Mallinckrodt ARD LLC and

Mallinckrodt plc

SCHNEIDER WALLACE COTTRELL
KONECKY LLP

Todd M. Schneider (SBN 158253)

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tschneider@schneiderwallace.com

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kbates@schneiderwallace.com

Attorneys for Plaintiff

Health Care Service Corporation

[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**STIPULATION TO EXTEND
DEADLINE FOR DEFENDANTS TO
FILE DEMURRER OR ANSWER
COMPLAINT AND [PROPOSED]
ORDER**

Dept: 23

Judge: Hon. Brad Seligman

Action Filed: February 27, 2020

1 **WHEREAS**, Plaintiff Health Care Service Corp. (“HCSC”) filed its Complaint in this
2 action on February 27, 2020 and personally served the Summons and Complaint on Defendants
3 Mallinckrodt ARD, LLC and Mallinckrodt plc (collectively “Mallinckrodt”) on March 5, 2020.

4 **WHEREAS**, absent any further extension arising from the emergency closure of the Court
5 due to the coronavirus pandemic, Mallinckrodt’s answer or demurrer currently is due by May 4,
6 2020, under the Presiding Judge Tara M. Desautels’s April 3, 2020 Order which declared every
7 day until May 1, 2020 a holiday for purposes of calculating deadlines.

8 **WHEREAS**, HCSC provisionally designated, and Mallinckrodt does not oppose the
9 designation of, this case as complex, given that the Complaint asserts claims under the antitrust,
10 unfair business practices, and anti-fraud statutes of California and over 30 other states, that HCSC
11 seeks hundreds of millions of dollars in damages, and that other actions involving similar claims
12 are pending in a few other courts around the country.

13 **WHEREAS**, this case has been assigned to Department 23 pending (a) a hearing in
14 Department 23 on the preliminary designation of the case as complex, a hearing which, due to the
15 coronavirus pandemic, has been continued from April 6, 2020 to May 5, 2020 and (b) assignment
16 of this case to a complex or general civil department of this Court for all purposes.

17 **WHEREAS**, HCSC and Mallinckrodt have met and conferred regarding the substance of
18 HCSC’s Complaint, Mallinckrodt plans to respond to the Complaint by filing a demurrer, and the
19 parties would like to establish an appropriate schedule for briefing the demurrer, even as the
20 coronavirus pandemic prevents and may continue to prevent related filings and new motion
21 practice.

22 **WHEREAS**, HCSC and Mallinckrodt believe that an extension of page limits for briefing
23 in relation to the demurrer is appropriate in light of the facts that the Complaint contains hundreds
24 of allegations regarding five categories of conduct and nine counts asserting antitrust, unfair trade
25 practices, insurance fraud and civil RICO theories under over thirty states’ laws.

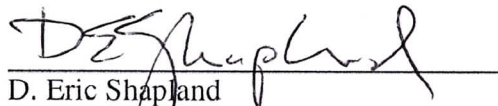
26 **NOW THEREFORE**, pursuant to Cal. R. Court, Rules 3.501(17) and 3.503, the parties
27 submit this Stipulation and [Proposed] Order and request the Court’s consent to:
28

- (a) continue the deadline for Mallinckrodt to serve and (if the Court is accepting such filings) file a demurrer to the Complaint in the above-titled action until Wednesday, May 20, 2020, and extend the page limit for the brief in support of the demurrer to 25 pages;
- (b) establish deadline for HCSC to serve and (if the Court is accepting such filings) file any brief in opposition to a demurrer of a June 5, 2020, and extend the page limit for that brief to 25 pages;
- (c) establish a deadline for Mallinckrodt to serve and (if the Court is accepting such filings) file a reply in support of the a demurrer of June 19, 2020, and extend the page limit for that brief to 12 pages; and
- (d) consideration with the Court at the first Case Management Conference in this matter, which is currently set for May 19, 2020, of both (i) an appropriate date for filing any demurrer-related papers that may have been served on a date on which the Court was not accepting filings and (ii) a date for hearing on the demurrer.

IT IS SO STIPULATED.

Dated: April 30, 2020

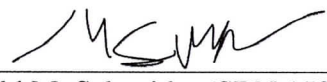
By:


D. Eric Shapland
**ARNOLD & PORTER KAYE
SCHOLER LLP**
777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
Telephone: (213) 243-4000
Facsimile: (213) 243-4199
eric.shapland@arnoldporter.com

*Attorneys for Defendant Mallinckrodt ARD
LLC and Mallinckrodt plc*

Dated: April 30, 2020

By:


Todd M. Schneider (SBN 158253)
Jason H. Kim (SBN 220279)
Matthew S. Weiler (SBN 236052)
Kyle G. Bates (SBN 299114)
**SCHNEIDER WALLACE
COTTRELL KONECKY LLP**
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Renee A. Nolan (*PHV* to be filed)
100 Front Street, Suite 520
West Conshohocken, PA 19428
Telephone: (215) 399-4770
molan@lowey.com

*Counsel for Plaintiff Health Care Service
Corporation*

IT IS SO ORDERED:

Dated: _____

By: _____
JUDGE OF THE SUPERIOR COURT
FOR THE COUNTY OF ALAMEDA



Superior Court of California, County of Alameda
 Rene C. Davidson Alameda County Courthouse
 1225 Fallon Street
 Oakland, CA 94612

Receipt Nbr: 918182
 Clerk: mbanks
 Date: 05/04/2020

Type	Case Number	Description	Amount
Filing	RG20056354	Extension of Time to Respond to Com	\$20.00

Total Amount Due: \$20.00
 Prior Payment:
 Current Payment: \$20.00
 Balance Due: \$.00
 Overage:
 Excess Fee:
 Change:

Payment Method:
 Cash:
 Check: \$20.00

EXHIBIT 12

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp	No. RG20056354
Plaintiff/Petitioner(s)	
VS.	Minutes
Mallinckrodt ARD LLC	
Defendant/Respondent(s)	
(Abbreviated Title)	

Department 23

Honorable Brad Seligman , Judge

Cause called for: Complex Determination Hearing on May 05, 2020.

COMPLEX DETERMINATION

The Court designates this case as complex pursuant to Rule 3.400 et seq. of the California Rules of Court. Counsel are advised to be familiar with the Alameda County Local Rules concerning complex litigation, including Rule 3.250 et seq. An order assigning the case to one of the three complex judges and an initial case management order will be issued.

COMPLEX CASE FEES

Pursuant to Government Code section 70616, any non-exempt party who has appeared in the action but has not paid the complex case fee is required to pay the fee within ten days of the filing of this order. The complex case fee is \$1,000 for each plaintiff or group of plaintiffs appearing together and \$1,000 PER PARTY for each defendant, intervenor, respondent or other adverse party, whether filing separately or jointly, up to a maximum of \$18,000 for all adverse parties. All payments must identify on whose behalf the fee is submitted. Please submit payment to the attention of the Complex Litigation Clerk located in the Civil Division at the Rene C. Davidson Courthouse, 1225 Fallon Street, Oakland, CA 94612. Please make check(s) payable to the Clerk of the Superior Court. Documents may continue to be filed as allowed under Local Rule 1.9. Note that for those admitted pro hac vice, there is also an annual fee. (Gov't Code section 70617.)

PROCEDURES

Calendar information, filings, and tentative rulings are available to the public at <http://www.alameda.courts.ca.gov/domainweb/>. All counsel are expected to be familiar and to comply with pertinent provisions of the Code of Civil Procedure, the California Rules of Court, the Alameda County Superior Court Local Rules and the procedures outlined on the domain web page of the assigned department.

SERVICE OF THIS ORDER

Counsel for plaintiff(s) shall have a continuing obligation to serve a copy of this order on newly joined parties defendant not listed on the proof of service of this order and file proof of service. Each party defendant joining any third party cross-defendant shall have a continuing duty to serve a copy of this order on newly joined cross-defendants and to file proof of service.

Minutes of 05/05/2020
Entered on 05/05/2020

Chad Finke Executive Officer / Clerk of the Superior Court

By


digital

Deputy Clerk

EXHIBIT 13

Schneider Wallace Cottrell Konecky
 Wotkins LLP
 Attn: Schneider, Todd M.
 2000 Powell St.
 Suite 1400
 Emeryville, CA 94608 _____

Mallinckrodt ARD LLC

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Order

Complaint - Antitrust/Trade Regulation

The Complex Determination Hearing was set for hearing on 05/05/2020 at 03:00 PM in Department 23 before the Honorable Brad Seligman. The Tentative Ruling was published and has not been contested.

IT IS HEREBY ORDERED THAT:

The tentative ruling is affirmed as follows: **COMPLEX DETERMINATION**

The Court designates this case as complex pursuant to Rule 3.400 et seq. of the California Rules of Court. Counsel are advised to be familiar with the Alameda County Local Rules concerning complex litigation, including Rule 3.250 et seq. An order assigning the case to one of the three complex judges and an initial case management order will be issued.

COMPLEX CASE FEES

Pursuant to Government Code section 70616, any non-exempt party who has appeared in the action but has not paid the complex case fee is required to pay the fee within ten days of the filing of this order. The complex case fee is \$1,000 for each plaintiff or group of plaintiffs appearing together and \$1,000 PER PARTY for each defendant, intervenor, respondent or other adverse party, whether filing separately or jointly, up to a maximum of \$18,000 for all adverse parties. All payments must identify on whose behalf the fee is submitted. Please submit payment to the attention of the Complex Litigation Clerk located in the Civil Division at the Rene C. Davidson Courthouse, 1225 Fallon Street, Oakland, CA 94612. Please make check(s) payable to the Clerk of the Superior Court. Documents may continue to be filed as allowed under Local Rule 1.9. Note that for those admitted pro hac vice, there is also an annual fee. (Gov't Code section 70617.)

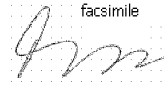
PROCEDURES

Calendar information, filings, and tentative rulings are available to the public at <http://www.alameda.courts.ca.gov/domainweb/>. All counsel are expected to be familiar and to comply with pertinent provisions of the Code of Civil Procedure, the California Rules of Court, the Alameda County Superior Court Local Rules and the procedures outlined on the domain web page of the assigned department.

SERVICE OF THIS ORDER

Counsel for plaintiff(s) shall have a continuing obligation to serve a copy of this order on newly joined parties defendant not listed on the proof of service of this order and file proof of service. Each party defendant joining any third party cross-defendant shall have a continuing duty to serve a copy of this order on newly joined cross-defendants and to file proof of service.

Dated: 05/05/2020

facsimile


Judge Brad Seligman

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Case Number: RG20056354
Order After Hearing Re: of 05/05/2020

DECLARATION OF SERVICE BY MAIL

I certify that I am not a party to this cause and that a true and correct copy of the foregoing document was mailed first class, postage prepaid, in a sealed envelope, addressed as shown on the foregoing document or on the attached, and that the mailing of the foregoing and execution of this certificate occurred at 1225 Fallon Street, Oakland, California.

Executed on 05/06/2020.

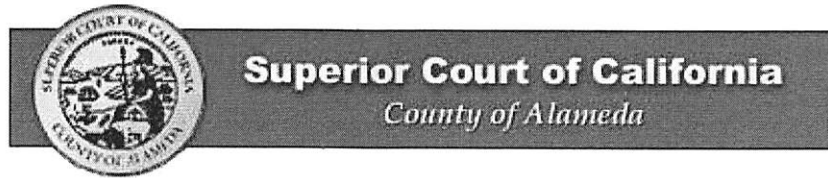
Chad Finke Executive Officer / Clerk of the Superior Court

By

A digital signature of Chad Finke, consisting of a stylized cursive script. Below the signature, the word "digital" is printed in a small, sans-serif font.

Deputy Clerk

EXHIBIT 14



Superior Court of California, County of Alameda
 Rene C. Davidson Alameda County Courthouse
 1225 Fallon Street
 Oakland, CA 94612

Receipt Nbr: 918738
 Clerk: ccollins
 Date: 05/08/2020

Type	Case Number	Description	Amount
Service	RG20056354	2 Complex Fee - Defendant Party(s)	\$2000.00

Total Amount Due: \$2,000.00
 Prior Payment:
 Current Payment: \$2,000.00
 Balance Due: \$.00
 Overage:
 Excess Fee:
 Change:

Payment Method:
 Cash:
 Check: \$2,000.00

Arnold & Porter

Eric Shapland
+1 213.243.4238 Direct
Eric.Shapland@arnoldporter.com

May 7, 2020

ENDORSED
FILED
ALAMEDA COUNTY

MAY 08 2020

CLERK OF THE SUPERIOR COURT
By *C. Collins* Deputy

VIA MESSENGER

Complex Litigation Clerk
Superior Court of the County of Alameda
Civil Division, Rene C. Davidson Courthouse
1225 Fallon Street
Oakland, CA 94612

Re: ***Health Care Service Corp. v. Mallinckrodt ARC LLC***
Case No. RG20056354

Dear Sir/Madam:

Enclosed please find a check in the amount of \$2000 for payment of complex fees on behalf of Defendants Mallinckrodt ARD LLC and Mallinckrodt plc in the above-referenced action. Please contact me if you have any questions.

Thank you.

Sincerely,

/s/ Eric Shapland
Eric Shapland

Enclosure

EXHIBIT 15

Superior Court of California, County of Alameda



Notice of Assignment of Judge for All Purposes

Case Number: RG20056354

Case Title: Health Care Service Corp VS Mallinckrodt ARD LLC

Date of Filing: 02/27/2020

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Pursuant to Rule 3.734 of the California Rules of Court and Title 3 Chapter 2 of the Local Rules of the Superior Court of California, County of Alameda, this action is hereby assigned by the Presiding Judge for all purposes to:

Judge:	Brad Seligman
Department:	23
Address:	Administration Building 1221 Oak Street Oakland CA 94612
Phone Number:	(510) 267-6939
Fax Number:	0
Email Address:	Dept.23@alameda.courts.ca.gov

Under direct calendaring, this case is assigned to a single judge for all purposes including trial.

Please note: In this case, any challenge pursuant to Code of Civil Procedure section 170.6 must be exercised within the time period provided by law. (See Code Civ. Proc. §§ 170.6, subd. (a)(2) and 1013.)

NOTICE OF NONAVAILABILITY OF COURT REPORTERS: Effective June 4, 2012, the court will not provide a court reporter for civil law and motion hearings, any other hearing or trial in civil departments, or any afternoon hearing in Department 201 (probate). Parties may arrange and pay for the attendance of a certified shorthand reporter. In limited jurisdiction cases, parties may request electronic recording.

Amended Local Rule 3.95 states: "Except as otherwise required by law, in general civil case and probate departments, the services of an official court reporter are not normally available. For civil trials, each party must serve and file a statement before the trial date indicating whether the party requests the presence of an official court reporter."

IT IS THE DUTY OF EACH PLAINTIFF AND CROSS COMPLAINANT TO SERVE A COPY OF THIS NOTICE IN ACCORDANCE WITH LOCAL RULES.

General Procedures

Following assignment of a civil case to a specific department, all pleadings, papers, forms, documents and writings can be submitted for filing at either Civil Clerk's Office, located at the René C. Davidson Courthouse, Room 109, 1225 Fallon Street, Oakland, California, 94612, and the Hayward Hall of Justice, 24405 Amador Street, Hayward, California, 94544. All documents, with the exception of the original summons and the original civil complaint, shall have clearly typed on the face page of each document, under the case number, the following:

ASSIGNED FOR ALL PURPOSES TO
JUDGE Brad Seligman
DEPARTMENT 23

All parties are expected to know and comply with the Local Rules of this Court, which are available on the court's website at: [http://www.alameda.courts.ca.gov/Pages.aspx/Local-Rules\(1\)](http://www.alameda.courts.ca.gov/Pages.aspx/Local-Rules(1)) and with the California Rules of Court, which are available at www.courtinfo.ca.gov.

Parties must meet and confer to discuss the effective use of mediation or other alternative dispute processes (ADR) prior to the Initial Case Management Conference. The court encourages parties to file a "Stipulation to Attend ADR and Delay Initial Case Management Conference for 90 Days". Plaintiff received that form in the ADR information package at the time the complaint was filed. The court's website also contains this form and other ADR information. If the parties do not stipulate to attend ADR, the parties must be prepared to discuss referral to ADR at the Initial Case Management Conference.

You may schedule case management hearings, law & motion hearings and other calendar events with Department 23 by EMAIL ONLY. The use of email is not a substitute for filing pleadings or filing other documents. You must provide copies of all email communications to each party (or the party's attorney if the party is represented) at the same time that you send the email to the Court and you must show that you have done so in your email. Courtesy copies of all moving, opposition and reply papers should be delivered directly to Dept. 23 in the Administration Building 1221 Oak St. 4th Floor Oakland, CA 94612.

Schedule for Department 23

The following scheduling information is subject to change at any time, without notice. Please contact the department at the phone number or email address noted above if you have questions.

- Trials generally are held: Mondays through Thursdays from 9:00 am - 1:30 pm.
- Case Management Conferences are held: Tuesdays beginning at 3:00 pm. and Fridays 9:15 am
- Law and Motion matters are heard: Tuesdays beginning at 3:00 pm. and Fridays 9:30 am; in exceptional circumstances, motions may be set at other times.
- Settlement Conferences are heard: N/A
- Ex Parte matters are heard: Tuesdays at 3:00 pm. and Fridays 9:00 am
- Reservations by email only. The court conducts discovery conferences pursuant to Local Rule 3.31 as described in the Initial Case Management Order issued in each case. No discovery motions will be scheduled prior to conference with the court. Email to schedule a conference. The email should briefly state the manner in which the parties have met and conferred.

Law and Motion Procedures

To obtain a hearing date for a Law and Motion or ex parte matter, parties must contact the department as follows:

- Motion Reservations

Email: Dept23@alameda.courts.ca.gov

Reservations by email only. (See Special Motion above)

- Ex Parte Matters

Email: Dept23@alameda.courts.ca.gov

Reservations by email only.

Tentative Rulings

The court may issue tentative rulings in accordance with the Local Rules. Tentative rulings will become the Court's order unless contested in accordance with the Local Rules. Tentative rulings will be available at:

- Website: www.alameda.courts.ca.gov/domainweb, Calendar Information for Dept. 23
- Phone: 1-866-223-2244

Dated: 05/07/2020



Facsimile

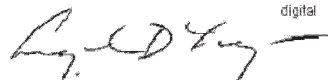
Presiding Judge,
Superior Court of California, County of Alameda

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice by placing copies in envelopes addressed as attached hereto and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 05/08/2020

By



digital

Deputy Clerk

SHORT TITLE: Health Care Service Corp VS Mallinckrodt ARD LLC	CASE NUMBER: RG20056354
--	----------------------------

ADDITIONAL ADDRESSEES

Schneider Wallace Cottrell Konecky
Wotkyns LLP
Attn: Schneider, Todd M.
2000 Powell St.
Suite 1400
Emeryville, CA 94608____

EXHIBIT 16

Schneider Wallace Cottrell Konecky
Wotkyns LLP
Attn: Schneider, Todd M.
2000 Powell St.
Suite 1400
Emeryville, CA 94608 _____

Mallinckrodt ARD LLC

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Stipulation and Order Re: Extension of
Time to Respond to Complaint Granted

IT IS ORDERED THAT Defendant's Stipulation and Order Re: Extension of Time to Respond to Complaint is granted, subject to the court's acceptance of new motions.

Defendant(s) Mallinckrodt PLC, Mallinckrodt ARD LLC may have until May 20, 2020 to file a responsive pleading in this action.

Dated: 05/12/2020

digital


Judge Brad Seligman

EXHIBIT 17

Todd M. Schneider (SBN 158253)

Jason H. Kim (SBN 220279)

Matthew S. Weiler (SBN 236052)

Kyle G. Bates (SBN 299114)

SCHNEIDER WALLACE

COTTRELL KONECKY LLP

2000 Powell Street, Suite 1400

Emeryville, CA 94608

Telephone: (415) 421-7100

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JKim@schneiderwallace.com

MWeiler@schneiderwallace.com

KBates@schneiderwallace.com

Peter D. St. Phillip (*Pro hac vice* to be filed)

LOWEY DANNENBERG, P.C.

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White Plains, NY 10601

Telephone: (914) 997-0500

PStPhillip@lowey.com

[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendants

Case No.: RG20056354

CASE MANAGEMENT CONFERENCE
STATEMENT FOR MAY 19, 2020 CASE
MANGEMENT CONFERENCE

I. INTRODUCTION

Plaintiff Health Care Service Corporation and Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (collectively “Mallinckrodt”) have met and conferred in advance of the Case Management Conference scheduled for May 19, 2020.

II. PLAINTIFF’S STATEMENT OF DISPUTED FACTUAL AND LEGAL ISSUES

Health Care Service Corp. (“HCSC”), a Blue Cross licensee that provides health care services and purchases pharmaceutical products for thousands of patients, brings claims under state and federal laws against Mallinckrodt relating to anticompetitive conduct and fraudulent sales and marketing practices for H.P. Acthar Gel (“Acthar”). Acthar is an adrenocorticotrophic hormone (“ACTH”) treatment with humble beginnings. Although available since 1952, the price leapt 97,500% from 2001 (when it cost \$40 a vial) to 2018 (when that same vial cost over \$39,000). Acthar is a critical treatment, used to control infant seizures, and is derived from the pituitary gland of pigs.

HCSC alleges this price increase is the result of a complex, multipart scheme involving monopoly, the abuse of exclusive distribution agreements, bribery, racketeering, fraud, and other deceptive and unfair practices that have imposed exorbitant costs on those financially responsible for the costs of the drug, including third-party payors (“TPPs”) like HCSC here. No other explanation exists for these unconscionable price increases, which by far outstrip the prices of any inputs, such as pigs.

Mallinckrodt manufactures Acthar and orchestrated a monopoly in the market for ACTH drugs, through its control of pricing and distribution of Acthar. Mallinckrodt’s predecessor, Questcor Pharmaceuticals, Inc. (“Questcor”), initiated a series of escalating price increases, while at the same time taking measures to ensure that competing ACTH products and channels of distribution were eliminated.

Starting in 2007, CuraScript SD became the exclusive distributor of Acthar. Questcor/Mallinckrodt consolidated this control by operating Express Scripts in a vertically integrated operation. This dynamic allowed Questcor/Mallinckrodt to control prices of Acthar. In

2013, Questcor acquired the rights to develop a synthetic ACTH drug called Synacthen Depot (“Synacthen”). Through Questcor, Mallinckrodt kept Synacthen off the market by out-bidding potential buyers and has ‘mothballed’ Synacthen after acquiring it.

Mallinckrodt’s campaign of fraudulent sales and marketing further inflated prices. Mallinckrodt used a charitable foundation, the Chronic Disease Fund (“CDF”), for the illegal purpose of paying patient co-pays. Mallinckrodt financed CDF and used it to expand the prescription base of Acthar beyond infant spasms. Mallinckrodt promoted “off label” use of Acthar to further increase its consumption, encouraging unproven daily dosing regimens that were ineffective but highly lucrative. To encourage wider prescription, Mallinckrodt developed a dosing regimen that only required patients to use Acthar for five days, even though there was no clinical evidence that the five-day dosing regimen was effective. This dosing regimen was not FDA approved or indicated on the Acthar label. This dosing protocol had a two-fold effect: (1) patients reported fewer side effects, lending credibility to Mallinckrodt’s unsupported claim of superior tolerability for Acthar when compared to steroids; and (2) the price seemed affordable when compared with the cost of administering the drug according to the label’s instructions. Finally, Mallinckrodt funneled millions of dollars to doctors under the guise of speaking engagements and sham clinical research studies to promote the foregoing. These payments were necessary because Acthar is expensive, requires refrigeration unlike other pill treatments, and needs to be injected into the body. HCSC contends that under the circumstances these payments are ‘bribes’ and not legitimate education or marketing programs.

The foregoing facts give rise to the following legal issues:

1. Whether Defendant fraudulently concealed any of the foregoing facts.
2. Whether Defendant violated New Jersey’s Racketeer Influenced and Corrupt Organizations Act (“NJ RICO”), N.J.S.A. §§ 2C:41-1(b), 2C:41-2(c), et al.
3. Whether Defendant violated Section 2C:41-2(d) of NJ RICO by conspiring to engage in the foregoing acts.
4. Whether Defendant violated state antitrust laws by monopolizing the market for ACTH.

5. Whether Defendant violated state antitrust law by entering into agreements in restraint of trade relating to Acthar.
6. Whether Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes.
7. Whether Defendant's conduct constitutes fraud under state laws.
8. Whether Defendants violated state insurance fraud laws.

III. DEFENDANTS' STATEMENT OF DISPUTED FACTUAL AND LEGAL ISSUES

HCSC is one of the nation's largest healthcare insurers. It claims that for eight years it paid too much for too many prescriptions for Acthar® Gel ("Acthar"), despite having contemporaneously reviewed for medical necessity each Acthar prescription that it covered. (Cmplt. ¶ 16, ¶ 271.) Acthar is a unique, complex injectable biopharmaceutical product that is approved by the FDA for use in nineteen serious and hard-to-treat rare medical conditions, such as infantile spasms, lupus, multiple sclerosis, nephrotic syndrome, and rheumatoid arthritis. While HCSC labels a 2007 price increase for Acthar "price gouging," HCSC admits that Mallinckrodt's predecessor-in-interest Questcor Pharmaceuticals, Inc. ("Questcor") raised the price to pull Acthar out of, as HCSC describes it, a "financial sinkhole" to "save" the product from being removed from the marketplace. (Cmplt. ¶¶ 7-9.) Thereafter, the price of Acthar has risen at only five percent per year, not counting inflation. (*Id.*)

Saving Acthar was critically important for the small patient population that needs it. Questcor's 2007 price increase was necessary to make manufacturing and selling the injectable specialty therapy viable. Questcor (and later Mallinckrodt, which acquired Acthar in 2014) made significant investments in medical research into the product's safety and efficacy for existing and new indications as well as educating prescribers about Acthar's FDA-approved indications so the therapy is appropriately prescribed to the patients for whom it is a suitable treatment. Questcor also improved the distribution system for Acthar by shifting to a specialty-pharmaceutical distribution model, which provides greater care, speed, and expertise in ensuring this perishable specialty therapeutic is efficiently delivered to patients who need it urgently. As is typical for specialty pharmaceutical

1 products, Questcor also established a patient support program, or “hub,” that helps patients for whom
2 Acthar has been prescribed submit claims for insurance coverage, appeal denials of coverage, secure
3 financial assistance with co-payment obligations, coordinate home delivery, and provides injection
4 training and support.

5 HCSC attempts to recast Acthar’s turnaround as the result of illegal monopoly, bribery,
6 racketeering, and fraud by Questcor, after it purchased the rights to Acthar in 2001, and later by
7 Mallinckrodt, which Defendant Mallinckrodt plc purchased from Questcor in 2014. In essence,
8 HCSC’s suit seeks to retroactively renegotiate the price it paid over the last eight years for medically
9 necessary prescriptions. Once stripped of HCSC’s incendiary labels, none of the categories of alleged
10 misconduct supports the Complaint’s nine counts under forty states’ laws.

11 HCSC complains about Questcor’s enhancements to the distribution system for Acthar using
12 nefarious phrases like “exclusive” and “vertically integrated operation,” but exclusive distribution and
13 other “vertical” agreements are presumptively procompetitive.

14 HCSC further alleges that Questcor violated 32 states’ antitrust laws when, in June 2013,
15 Questcor acquired the development rights to a synthetic ACTH product called Synacthen Depot
16 (“Synacthen”), which is not FDA approved, and thus secured an illegal monopoly in the “ACTH drug
17 market.” But HCSC’s alleged market definition is legally deficient, and HCSC does not and cannot
18 plead injury resulting from the acquisition. If these claims were not subject to dismissal, the
19 appropriate relevant antitrust market, Synacthen’s realistic prospects for FDA approval and whether
20 there would be any resulting effect on competition and HCSC would be issues in dispute.

21 HCSC also complains that Mallinckrodt has funded programs that help patients insured by
22 HCSC who have been prescribed Acthar pay their co-payments for the therapy. But Mallinckrodt’s
23 conduct in regard to those programs was lawful and consistent with relevant industry guidance, and
24 HCSC fails to state a claim otherwise; in any event, because the alleged misconduct has been well
25 known since 2013, HCSC’s claims are time barred. Under these claims, Mallinckrodt’s intent to
26 operate in compliance with applicable laws, and the effect of co-payment assistance on utilization
27 would be issues in dispute.

1 Similarly, HCSC attempts to label Questcor's and Mallinckrodt's respective significant
2 investments in medical research and education from 2011 to the present as "bribes" paid to doctors in
3 exchange for writing Acthar prescriptions. But HCSC pleads no facts supporting that
4 mischaracterization. If these claims were not subject to dismissal, the parties would dispute whether
5 payments to doctors were legitimate compensation for services, whether prescriptions written by the
6 subject doctors were medically appropriate, and HCSC's policies and practices concerning coverage
7 of Acthar.

8 HCSC also alleges that Questcor promoted Acthar for an off-label dosing regimen to treat
9 multiple sclerosis. Doctors are, of course, free to prescribe off label. HCSC fails to identify with the
10 requisite particularity any unlawful promotional activity by anyone at Questcor or Mallinckrodt to any
11 particular doctor, let alone a connection between any such alleged promotion, reliance thereon, and
12 reimbursement by HCSC, which mandates dismissal of HCSC's fraud-based claims. If these claims
13 were not subject to dismissal, promotional activity by Questcor and Mallinckrodt for Acthar, and
14 HCSC's policies and practices concerning coverage of Acthar would be issues in dispute.

15 **IV. AGREED UPON AND DISPUTED CASE MANAGEMENT ISSUES**

16 The parties have met and conferred and, subject to the Court's approval, have agreed to a
17 briefing schedule for Defendant's demurrer to HCSC's complaint. On April 30, 2020 the parties
18 submitted a stipulation and proposed order to the Court on the schedule and an enlargement of page
19 limits to accommodate briefing the issues. Under the parties' proposal, (1) Defendant will serve and
20 lodge a 25-page demurrer on May 20, 2020; (2) HCSC will lodge and serve a 25-page opposition brief
21 on June 5, 2020; and (3) Defendant will lodge and serve a 12-page reply brief on June 19, 2020.

22 The parties request a hearing date at the Court's earliest convenience.

23 The parties agree that they will submit for entry by the Court a Protective Order, and
24 stipulations concerning electronically stored information ("ESI") and expert discovery. Should the
25 parties not agree on certain aspects of these orders, they will meet and confer to resolve their
26 differences and, if they cannot, they will submit proposed orders identifying where the parties are not
27 in agreement.

HCSA believes that discovery should commence following the Case Management Conference on May 19, 2020 and that the Court should enter a partial case schedule proposed below.

HCSC believes that periodic status conferences will help with the progress of this litigation. HCSC proposes that the Court conduct bi-monthly status conferences, and that the parties submit a statement outlining any outstanding issues one week before any scheduled conference. In light of the COVID-19 pandemic, which has impacted the Court and parties alike, HCSC proposes to conduct status conferences by video conference or some other method convenient to the Court. Based on Defendants' proposal, described below, to conduct "substantial" discovery against HCSC when the most germane issues with respect to HCSC will be the straight-forward matters of the nature and extent HCSC's purchases, HCSC anticipates that periodic conferences will assist the parties in conducting efficient and focused discovery.

Finally, whatever issues will be raised by Defendants in their forthcoming demurrer are not likely to be case-dispositive. The viability of HCSC's core theories of liability are well-established. That courts have, on the margins, reached different results with respect to certain aspects of claims that are similar to those alleged by HCSC here does not warrant delay in setting a case schedule or discovery deadlines. HCSC will meet and confer with Defendants to prioritize, for early discovery, documents that have already been produced in other litigation.

¹ Consolidated with *MSP Recovery Claims, et al. v. Mallinckrodt ARD LLC*, Case No. 18-cv-00379 (N.D. Ill.).

Date	Event
January 29, 2021	Fact discovery deadline
February 28, 2021	Plaintiff to produce expert reports
May 30, 2021	Defendants to produce expert reports
August 30, 2021	Summary judgment or summary adjudication deadline
TBD	Trial

B. Defendants' Position on Case Management Issues and Discovery

It would be a waste of the parties' and the Court's resources to rush headlong into discovery or set a case schedule without the benefit of the Court's ruling on Defendants' forthcoming demurrer and motion to strike. HCSC challenges five categories of conduct alleging nine separate counts under the laws of over forty different states, and it places at issue all Acthar prescriptions that HCSC covered back to 2011. As previewed above, there are several grounds on which to dismiss and/or strike the Complaint in its entirety. Mallinckrodt has cooperated with HCSC on a schedule by which to present those issues to the Court, notwithstanding delays occasioned by precautions to stop the spread of the coronavirus, so that the Court can consider those issues as soon as it is ready to resume hearing new demurrers. Courts addressing similar claims by other Acthar payors have substantially narrowed or dismissed the actions on the pleadings.²

² See *MSP Recovery Claims, Series LLC, et al. v. Mallinckrodt ARD Inc.*, No. 3:20-cv-50056 (N.D. Ill. Mar. 23, 2020) (dismissing, with leave to amend, complaint for failure to plead standing); *Humana Inc. v. Mallinckrodt ARD LLC*, No. CV 19-06926 (C.D. Cal. March 9, 2020) ("*Humana Order*") (dismissing, with leave to amend, antitrust and tortious interference—but allowing RICO, consumer protection, and common law—claims); *Acument Global Technologies, Inc. v. Mallinckrodt ARD, Inc.*, No. CT-2275-19 (Cir. Ct. Shelby Cty. Tenn. Feb. 21, 2020) (dismissing fraud and consumer protection, but allowing antitrust and unjust enrichment, claims); *Washington Cty. Bd. of Educ. v. Mallinckrodt ARD, Inc.*, ___ F. Supp. 3d ___, No. CV JKB-19-1854, 2020 WL 43016 (D. Md. Jan. 3, 2020) (dismissing action by rejecting fraud and consumer-protection claims); *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019) (dismissing RICO and common-law, but allowing antitrust, claims); but see *Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC*, No. 19-cv-03047 (E.D. Pa. Dec. 19, 2019) (denying, without an opinion,

1 Even if the Court were to determine that dismissal of the Complaint in its entirety is not
 2 warranted, elimination of entire categories of conduct or a narrowing of the damages period will have
 3 a substantial effect on the scope of appropriate discovery in this case. It thus makes sense to resolve
 4 the issues presented by Mallinckrodt's demurrer and motion to strike before commencing discovery in
 5 this action.

6 To the extent that the Court permits any of the claims to go forward, the parties can tailor their
 7 discovery to only those remaining claims, including the substantial discovery Mallinckrodt would
 8 need to take of HCSC. Initiating discovery now, without the benefit of the Court's ruling on
 9 Mallinckrodt's demurrer and motion to strike, will result in unnecessary and wasteful efforts by the
 10 parties to take discovery on legally deficient claims during a global pandemic the mitigation of which
 11 continues to impact the parties' businesses as well as potential witnesses, document custodians, and
 12 the like. For the same reasons, Mallinckrodt respectfully requests that the Court wait until after ruling
 13 on Mallinckrodt's demurrer and motion to strike before setting a schedule.

14 If the Court is inclined to set a schedule, Mallinckrodt respectfully requests that the Court enter
 15 the schedule below. HCSC's proposed schedule is based on the mistaken premise that fact discovery
 16 in the *Rockford* litigation, which is proceeding on antitrust claims challenging the distribution
 17 agreement and the Synacthen acquisition *only*, ends in September 2020. To the contrary, the court has
 18 extended all civil case deadlines in that district for at least 77 days.³ Accordingly, fact discovery in
 19 *Rockford* will not end until December 2020, at the earliest.

20 Furthermore, to the extent discovery is warranted here, Mallinckrodt agrees that discovery it
 21 has produced or may produce in the future in other Acthar-related cases will be responsive to HCSC's
 22 discovery requests in this case. But, HCSC's schedule does not adequately account for Mallinckrodt's
 23

24 motion to dismiss RICO, consumer-protection, and common-law claims); *Int'l Union of Operating*
 25 *Engineers Local 542 v. Mallinckrodt ARD, LLC*, No. 2018-14059 (Pa. Commw. Ct., Montgomery
 26 Cty. Jan. 8, 2019) (denying preliminary objections to antitrust-related theories of harm brought under
 27 consumer protection statute)

28 ³ *In re: Coronavirus COVID-19 Public Emergency* ¶ 2 (N.D. Ill. Arp. 24, 2020), available at
<https://www.ilnd.uscourts.gov/assets/documents/AMENDED%20GENERAL%20ORDER%2020-0012.pdf>

1 need to take substantial discovery of HCSC—one of nation’s largest healthcare insurers—on any
2 surviving claims. Accordingly, Mallinckrodt respectfully submits that, if the Court is inclined to enter
3 a schedule at this time, it enter the schedule below.

Date	Event
June 30, 2021	Fact discovery deadline
July 29, 2021	Plaintiff to produce expert reports
September 28, 2021	Defendants to produce expert reports
December 17, 2021	Motions for summary judgment or summary adjudication
TBD	Trial

Dated: May 12, 2020

Respectfully submitted:

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/s/ Matthew S. Weiler

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and Mallinckrodt plc*

Tyler B. Smith

From: RingCentral <service@ringcentral.com>
Sent: Tuesday, May 12, 2020 6:37 PM
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Here are the results of the 13-page fax you sent from your phone number **(855) 394-6767, Ext. 305**

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendants

Case No.: RG20056354

PROOF OF SERVICE

PROOF OF SERVICE

1 I, Tyler B. Smith, declare the following:

2 I am over the age of eighteen years and not a party to the within entitled action. I am
3 employed at Schneider Wallace Cottrell Konecky LLP located at 2000 Powell Street, Suite 1400,
4 Emeryville, CA 94608.

5 On May 12, 2020, I served the following document(s) described as:

- 6 • CASE MANAGEMENT CONFERENCE STATEMENT FOR MAY 19, 2020 CASE
7 MANGEMENT CONFERENCE
• FAX CONFIRMATION OF SENDING

8
9 on the following interested party(s):

10 D. Eric Shapland
ARNOLD & PORTER KAYE SCHOLER LLP
11 777 South Figueroa Street, 44th Floor
Los Angeles, CA 90017-5844
12 Telephone: (213) 243-4000
Facsimile: (213) 243-4199
13 eric.shapland@arnoldporter.com

14 [✓] **BY ELECTRONIC SERVICE** by electronically mailing a true and correct copy in PDF
15 format through SWCKW's electronic mail system to the email address(s) set forth above.

16 I declare under penalty of perjury under the laws of the State of California that the foregoing
17 is true and correct. Executed on May 12, 2020, at Emeryville, California.

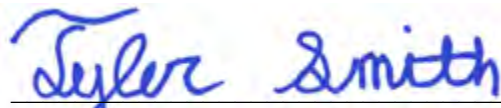
18
19
20 
21 Tyler B. Smith

EXHIBIT 18

ENDORSED
FILED
ALAMEDA COUNTY

MAY 15 2020

CLERK OF THE SUPERIOR COURT

By *C. Collins* Deputy

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3 Laura S. Shores (*PHV* to be filed)

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20 *Attorneys for Defendants*

21 *Mallinckrodt ARD LLC and Mallinckrodt plc*

22 SUPERIOR COURT OF THE STATE OF CALIFORNIA

23 COUNTY OF ALAMEDA

24 HEALTH CARE SERVICE CORP.,

25 Plaintiff,

26 v.

27 MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
28 ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**DEFENDANTS MALLINCKRODT
ARD LLC AND MALLINCKRODT
PLC'S PEREMPTORY
CHALLENGE PURSUANT TO
CODE CIV. PROC. § 170.6**

**DECLARATION OF D. ERIC
SHAPLAND IN SUPPORT
THEREOF**

[CCP § 170.61]

Action Filed: February 27, 2020

Dept: 23

Judge: Hon. Brad Seligman

DEFS. MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S PEREMPTORY CHALLENGE
PURSUANT TO CODE CIV. PROC. § 170.6; DECLARATION OF D. ERIC SHAPLAND

Ex. 18
p. 265

TO THE COURT, ALL PARTIES, AND THEIR ATTORNEYS OF RECORD:

Pursuant to Code of Civil Procedure § 170.6, Defendants Mallinckrodt ARD LLC and Mallinckrodt plc hereby move that this action, which has been assigned to the Honorable Judge Brad Seligman, be reassigned from Judge Seligman, and that no matters hereinafter arising in this action be heard or assigned to Judge Seligman. This Motion is made within 15 days of the Court's Notice of Assignment of Judge For All Purposes (Code Civ. Proc. § 170.6(a)(2)).

This Motion is based on the matters contained herein, the requirements of Code of Civil Procedure § 170.6, and the Declaration of D. Eric Shapland attached hereto.

Defendants request that the relief herein requested be granted.

Dated: May 15, 2020

Respectfully submitted,

ARNOLD & PORTER KAYE SCHOLER LLP

By:


D. Eric Shapland

Matthew M. Wolf (*PHV* to be filed)
Laura S. Shores (*PHV* to be filed)
Sonia Kuester Pfaffenroth
Michael B. Bernstein (*PHV* to be filed)
Adam M. Pergament

*Attorneys for Defendants
Mallinckrodt ARD LLC and
Mallinckrodt plc*

**DECLARATION OF D. ERIC SHAPLAND IN SUPPORT OF PEREMPTORY
CHALLENGE PURSUANT TO CODE OF CIVIL PROCEDURE SECTION 170.6**

I, D. Eric Shapland, declare as follows:

1. I am an attorney admitted to practice before the courts of the State of California and counsel with the law firm of Arnold & Porter Kaye Scholer LLP. My firm and I serve as counsel to Defendants Mallinckrodt ARD LLC and Mallinckrodt plc ("Mallinckrodt") in the above-captioned action.

2. I make this declaration in support of Mallinckrodt's Motion for Peremptory Challenge of the Honorable Judge Brad Seligman pursuant to Code of Civil Procedure § 170.6. The facts stated herein are based upon my personal knowledge and, if called upon to testify thereto, I could and would competently do so.

3. On May 7, 2020, the Court issued a notice assigning the above-captioned action to Judge Brad Seligman for all purposes.

4. I declare that Judge Brad Seligman is prejudiced against me or my client or my client's interests, such that I believe that my client cannot have a fair and impartial trial or hearing before Judge Seligman.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 15 day of May 2020, at Los Angeles, California.


D. Eric Shapland

PROOF OF SERVICE

1. I am over eighteen years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 777 South Figueroa Street, Forty-Fourth Floor, Los Angeles, California 90017-5844.

2. On May 15, 2020, I served the following document(s):

**DEFENDANTS MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S
PEREMPTORY CHALLENGE PURSUANT TO CODE CIV. PROC. § 170.6;
DECLARATION OF D. ERIC SHAPLAND IN SUPPORT THEREOF**

3. I served the document(s) on the following person(s):

[SEE ATTACHED SERVICE LIST]

4. The documents were served by the following means:

☐ **By U.S. Mail.** I enclosed the document(s) in a sealed envelope or package addressed to the person(s) at the address(es) in Item 3 and (check one):

☐ deposited the sealed envelope with the United States Postal Service, with the postage fully prepaid.

☐ placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for mailing. On the same day the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

I am employed in the county where the mailing occurred. The envelope or package was placed in the mail at Los Angeles, California.

☐ **By Overnight Delivery/Express Mail.** I enclosed the documents and an unsigned copy of this declaration in a sealed envelope or package designated by [name of delivery company or U.S. Postal Service for Express Mail] addressed to the persons at the address(es) listed in Item 3, with [Express Mail postage or, if not Express Mail, delivery fees] prepaid or provided for. I placed the sealed envelope or package for collection and delivery, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for express delivery. On the same day the correspondence is collected for delivery, it is placed for collection in the ordinary course of business in a box regularly maintained by [name of delivery company or U.S. Postal Service for Express Mail] or delivered to a courier or driver authorized by [name of delivery company] to receive documents.

☐ **By Messenger Service.** I served the documents by placing them in an envelope or package addressed to the persons at the address(es) listed in Item 3 and providing them to a professional messenger service for service. (See attached Declaration(s) of Messenger.)

- 1 ☐ **By Facsimile Transmission.** Based on an agreement between the parties to accept service
 2 by facsimile transmission, which was confirmed in writing, I faxed the document(s) and an
 3 unsigned copy of this declaration to the person(s) at the facsimile numbers listed in Item 3
 4 on May 15, 2020, at [type time]. The transmission was reported as complete without error
 5 by a transmission report issued by the facsimile machine that I used immediately following
 6 the transmission. A true and correct copy of the facsimile transmission report, which I
 7 printed out, is attached hereto.
- 8 ☒ **By Electronic Service (E-mail).** Based on California Rule of Court 2.251(c)(3), or on a
 9 court order, or on an agreement of the parties to accept service by electronic transmission, I
 10 transmitted the document(s) to the person(s) at the electronic notification address(es) listed
 11 in Item 3 on May 15, 2020.
- 12 ☐ **Via Court Notice of Electronic Filing.** The document(s) will be served by the court via
 13 NEF and hyperlink to the document(s). On May 15, 2020, I checked the CM/ECF docket
 14 for this case or adversary proceeding and determined that the person(s) listed in Item 3 are
 15 on the Electronic Mail Notice List to receive NEF transmission at the email addresses
 16 indicated in Item 3 [or on the attached service list, if applicable].
- 17 ☐ **Via Electronic Notification.** The document(s) will be served via electronic notification on
 18 May 15, 2020 on the person(s) listed in Item 3 at the email addresses indicated in Item 3
 19 [or on the attached service list, if applicable].
- 20 ☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the
 21 foregoing is true and correct.
- 22 ☐ **FEDERAL:** I declare that I am employed in the office of a member of the bar of this court
 23 at whose direction the service was made.

24 Dated: May 15, 2020.

25 Signature: _____

26 Type or Print Name: Kathryn Jensen

27 E-Service Address:

28 kathryn.jensen@arnoldporter.com

Health Care Service Corp. v. Mallinckrodt ARD LLC, etc., et al.
Alameda Superior Court Case No. RG20056354

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EXHIBIT 19

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Tentative Case Management Order

This Tentative Case Management Order is issued by Judge Brad Seligman on 05/18/2020.

ORDER re: CASE MANAGEMENT

The Court has ordered the following after review of the case, including timely filed Case Management Statements, without a conference.

FURTHER CONFERENCE

A further Case Management Conference is scheduled for 06/24/2020 at 09:00 AM in Dept. 23.

Updated Case Management Statements in compliance with Rule of Court 3.725, must be filed no later than 5 days before the hearing. If the foregoing date is a court holiday or a weekend, the time is extended to the next business day.

OTHER ORDERS

1. Parties should promptly file motion papers and **request a reservation # for 6/24** for pleadings motions.
2. If after meeting and conferring the parties cannot resolve discovery issues, an email should be sent to the clerk requesting a discovery conference. The court will address an overall discovery schedule at the next CMC (and requests the parties to outline their discovery plans). While the court does not issue a stay on discovery at this time, it expects the parties to engage in focused, limited discovery prior to the 6/24 hearing.

NOTICES

The Court orders counsel and/or self-represented parties to obtain a copy of this order from the court's website <http://www.alameda.courts.ca.gov/domainweb>.

Any delay in the trial, caused by non-compliance with any order contained herein, shall be the subject of sanctions pursuant to CCP 177.5.

EXHIBIT 20

EXHIBIT 21

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Case Management Order

Date: 05/19/2020

Time: 03:00 PM

Dept: 23

Judge: Brad Seligman

ORDER re: CASE MANAGEMENT

The Court has ordered the following after review of the case, including timely filed Case Management Statements, without a conference.

FURTHER CONFERENCE

A further Case Management Conference is scheduled for 06/24/2020 at 09:00 AM in Dept. 23.

Updated Case Management Statements in compliance with Rule of Court 3.725, must be filed no later than 5 days before the hearing. If the foregoing date is a court holiday or a weekend, the time is extended to the next business day.

OTHER ORDERS

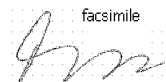
1. Parties should promptly file motion papers and request a reservation # for 6/24 for pleadings motions.
2. If after meeting and conferring the parties cannot resolve discovery issues, an email should be sent to the clerk requesting a discovery conference. The court will address an overall discovery schedule at the next CMC (and requests the parties to outline their discovery plans). While the court does not issue a stay on discovery at this time, it expects the parties to engage in focused, limited discovery prior to the 6/24 hearing.

NOTICES

The Court orders counsel and/or self-represented parties to obtain a copy of this order from the court's website <http://www.alameda.courts.ca.gov/domainweb>.

Any delay in the trial, caused by non-compliance with any order contained herein, shall be the subject of sanctions pursuant to CCP 177.5.

Dated: 05/19/2020

facsimile


Judge Brad Seligman

EXHIBIT 22



22713476



SCHNEIDER WALLACE
COTTRELL KONECKY LLP

May 12, 2020

VIA U.S. MAIL

Clerk of the Court
Superior Court of California, County of Alameda
1221 Oak Street
Oakland, CA 94612

FILED
ALAMEDA COUNTY

MAY 20 2020

CLERK OF THE SUPERIOR COURT
By 
Deputy

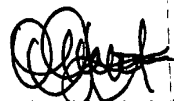
Re: HCSC v. Mallinkrodt Ard, LLC, et al.
Superior Court of California, County of Alameda
Case No. RG20056354

Dear Clerk:

Enclosed is check number 19119, in the amount of \$1,000.00, which shall serve as payment toward the complex filing fee in the above-referenced matter.

Sincerely,

SCHNEIDER WALLACE
COTTRELL KONECKY
WOTKYN'S LLP


Onyebuchi Okeke
Legal Secretary

RECEIVED
MAY 20 2020
ALAMEDA COUNTY SUPERIOR COURT

Enclosure.

EXHIBIT 23

Superior Court of California, County of Alameda



Notice of Reassignment of Judge for All Purposes

Case Number: RG20056354

Case Title: Health Care Service Corp VS Mallinckrodt ARD LLC

Date of Filing: 02/27/2020

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

Pursuant to Rule 3.734 of the California Rules of Court and Title 3 Chapter 2 of the Local Rules of the Superior Court of California, County of Alameda, this action is hereby reassigned by the Presiding Judge for all purposes to:

Judge:	Stephen Kaus
Department:	19
Address:	Administration Building 1221 Oak Street Oakland CA 94612
Phone Number:	(510) 267-6935
Fax Number:	
Email Address:	Dept.19@alameda.courts.ca.gov

Under direct calendaring, this case is assigned to a single judge for all purposes including trial.

Please note: In this case, any challenge pursuant to Code of Civil Procedure section 170.6 must be exercised within the time period provided by law. (See Code Civ. Proc. §§ 170.6, subd. (a)(2) and 1013.)

NOTICE OF NONAVAILABILITY OF COURT REPORTERS: Effective June 4, 2012, the court will not provide a court reporter for civil law and motion hearings, any other hearing or trial in civil departments, or any afternoon hearing in Department 201 (probate). Parties may arrange and pay for the attendance of a certified shorthand reporter. In limited jurisdiction cases, parties may request electronic recording.

Amended Local Rule 3.95 states: "Except as otherwise required by law, in general civil case and probate departments, the services of an official court reporter are not normally available. For civil trials, each party must serve and file a statement before the trial date indicating whether the party requests the presence of an official court reporter."

IT IS THE DUTY OF EACH PLAINTIFF AND CROSS COMPLAINANT TO SERVE A COPY OF THIS NOTICE IN ACCORDANCE WITH LOCAL RULES.

General Procedures

Following assignment of a civil case to a specific department, all pleadings, papers, forms, documents and writings can be submitted for filing at either Civil Clerk's Office, located at the René C. Davidson Courthouse, Room 109, 1225 Fallon Street, Oakland, California, 94612, and the Hayward Hall of Justice, 24405 Amador Street, Hayward, California, 94544. All documents, with the exception of the original summons and the original civil complaint, shall have clearly typed on the face page of each document, under the case number, the following:

ASSIGNED FOR ALL PURPOSES TO
JUDGE Stephen Kaus
DEPARTMENT 19

All parties are expected to know and comply with the Local Rules of this Court, which are available on the court's website at: [http://www.alameda.courts.ca.gov/Pages.aspx/Local-Rules\(1\)](http://www.alameda.courts.ca.gov/Pages.aspx/Local-Rules(1)) and with the California Rules of Court, which are available at www.courtinfo.ca.gov.

Parties must meet and confer to discuss the effective use of mediation or other alternative dispute processes (ADR) prior to the Initial Case Management Conference. The court encourages parties to file a "Stipulation to Attend ADR and Delay Initial Case Management Conference for 90 Days". Plaintiff received that form in the ADR information package at the time the complaint was filed. The court's website also contains this form and other ADR information. If the parties do not stipulate to attend ADR, the parties must be prepared to discuss referral to ADR at the Initial Case Management Conference.

You may schedule case management hearings, law & motion hearings and other calendar events with Dept. 19 by e-mail. The use of e-mail is not a substitute for filing pleadings or filing other documents. You must provide copies of all email communications to each party (or the party's attorney if the party is represented) at the same time that you send the e-mail to the Court and you must show that you have done so in your e-mail.

Courtesy copies of all moving, opposition and reply papers should be delivered directly to Dept. 19 in the Administration Building, 1221 Oak St. 3rd floor Oakland, CA 94612

Schedule for Department 19

The following scheduling information is subject to change at any time, without notice. Please contact the department at the phone number or email address noted above if you have questions.

- Trials generally are held: Monday through Thursday at 8:30 a.m. to 1:30 p.m.
- Case Management Conferences are held: Tuesday at 3:00 p.m.
- Law and Motion matters are heard: Mondays and Wednesdays at 3:00 p.m.
- Settlement Conferences are heard: As Scheduled by Judge
- Ex Parte matters are heard: Mondays and Wednesdays at 3:00pm
- Civil Jury Trial Readiness Hearings heard on Fridays at 2:00 p.m.

Law and Motion Procedures

To obtain a hearing date for a Law and Motion or ex parte matter, parties must contact the department as follows:

- Motion Reservations

Email: Dept.19@alameda.courts.ca.gov

Please provide: 1) Name of case; 2) Case number; 3) Title of motion; 4) Moving party; 5) Name of Responding Party's Counsel and email address.

- Ex Parte Matters

Email: Dept19@alameda.courts.ca.gov

Tentative Rulings

The court may issue tentative rulings in accordance with the Local Rules. Tentative rulings will become the Court's order unless contested in accordance with the Local Rules. Tentative rulings will be available at:

- Website: www.alameda.courts.ca.gov/domainweb, Calendar Information for Dept. 19
- Phone: 1-866-223-2244

Dated: 05/21/2020



Presiding Judge,

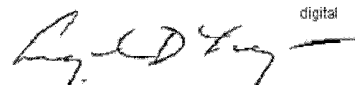
Superior Court of California, County of Alameda

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice by placing copies in envelopes addressed as attached hereto and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 05/22/2020

By



Deputy Clerk

SHORT TITLE: Health Care Service Corp VS Mallinckrodt ARD LLC	CASE NUMBER: RG20056354
--	----------------------------

ADDITIONAL ADDRESSEES

Schneider Wallace Cottrell Konecky
Wotkyns LLP
Attn: Schneider, Todd M.
2000 Powell St.
Suite 1400
Emeryville, CA 94608____

EXHIBIT 24

Schneider Wallace Cottrell Konecky
Wotkyns LLP
Attn: Schneider, Todd M.
2000 Powell St.
Suite 1400
Emeryville, CA 94608 _____

Mallinckrodt ARD LLC

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Declaration Re: Peremptory Challenge
as to Brad Seligman Granted

IT IS ORDERED that the Defendant's Declaration Re: Peremptory Challenge as to Brad Seligman is granted.

Dated: 05/21/2020

digital


Judge Brad Seligman

EXHIBIT 25

F Schneider Wallace Cottrell Konecky Wotkyns LLP Attn: Schneider, Todd M. 2000 Powell St. L Suite 1400 Emeryville, CA 94608____	F Mallinckrodt ARD LLC L
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Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp VS. Mallinckrodt ARD LLC	Plaintiff/Petitioner(s) Defendant/Respondent(s) (Abbreviated Title)
---	---

No. RG20056354

NOTICE OF HEARING (AMENDED)

Case Management Conf Continuance on
 06/24/2020 has been vacated and rescheduled.

To each party or to the attorney(s) of record for each party herein:

Notice is hereby given that the above entitled action has been set for:

Case Management Conf Continuance

You are hereby notified to appear at the following Court location on the date and time noted below:

Case Management Conf Continuance:

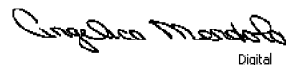
DATE: 06/23/2020 TIME: 03:00 PM DEPARTMENT: 19

LOCATION: Administration Building, Third Floor
 1221 Oak Street, Oakland

Dated: 05/26/2020

Chad Finke Executive Officer / Clerk of the Superior Court

By


Digital

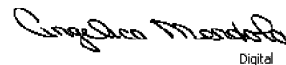
Deputy Clerk

CLERK'S CERTIFICATE OF MAILING

I certify that the following is true and correct: I am the clerk of the above-named court and not a party to this cause. I served this Notice by placing copies in envelopes addressed as shown hereon and then by sealing and placing them for collection, stamping or metering with prepaid postage, and mailing on the date stated below, in the United States mail at Alameda County, California, following standard court practices.

Executed on 05/26/2020.

By


Digital

Deputy Clerk

EXHIBIT 26

ENDORSED
FILED
ALAMEDA COUNTY
MAY 28 2020
CLERK OF THE SUPERIOR COURT
By Jessica Flaw Deputy

ARNOLD & PORTER KAYE SCHOLER LLP

Matthew M. Wolf (*PHV* to be filed)

Laura S. Shores (*PHV* to be filed)

Sonia Kuester Pfaffenroth (SBN 223984)

Michael B. Bernstein (*PHV* to be filed)

Adam M. Pergament (SBN 267557)

601 Massachusetts Avenue, N.W.

Washington, D.C. 20001-3743

Telephone: (202) 942-5000

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laura.shores@arnoldporter.com

sonia.pfaffenroth@arnoldporter.com

michael.b.bernstein@arnoldporter.com

adam.pergament@arnoldporter.com

D. Eric Shapland (SBN 193853)

777 South Figueroa Street, 44th Floor

Los Angeles, CA 90017-5844

Telephone: (213) 243-4000

Facsimile: (213) 243-4199

eric.shapland@arnoldporter.com

Attorneys for Defendants

Mallinckrodt ARD LLC and Mallinckrodt plc

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**THE DEFENDANT
MALLINCKRODT ENTITIES'
NOTICE OF DEMURRER AND
DEMURRER TO HCSC'S
COMPLAINT; SHAPLAND
DECLARATION**

Date: Aug. 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Reservation No. R-2179414

Action Filed: February 27, 2020

BY FAX

NOTICE OF DEMURRER

TO THE COURT, ALL INTERESTED PARTIES, AND COUNSEL OF RECORD:

PLEASE TAKE NOTICE that, on August 5, 2020 at 3:00 pm, or as soon thereafter as the matter may be heard, in Department 19 of this Court's Complex Division, located at 1221 Oak Street, 3rd Floor, Oakland, CA 94612, defendants Mallinckrodt ARD LLC and Mallinckrodt plc ("Mallinckrodt") will and hereby do demur to plaintiff Health Care Service Corporation's ("HCSC") Complaint, pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a).

Mallinckrodt demurs to the Complaint on the following grounds:

- **Demurrer to Count One (New Jersey RICO Act):** Count One fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Two (Conspiracy to Violate New Jersey RICO Act):** Count Two fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Three (Monopolization under 28 States' Laws):** Count Three fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Four (Restraint of Trade under 31 States' Laws):** Count Four fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Five (Unfair and Deceptive Practices Acts under 34 States' Laws):** Count Five fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Six (Fraud):** Count Six fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Seven (Insurance Fraud Statutes under 40 States' Laws):** Count Seven fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Eight (Tortious Interference with Contractual Relations):** Count Eight fails to state facts sufficient to constitute a cause of action.
- **Demurrer to Count Nine (Unjust Enrichment):** Count Nine fails to state facts sufficient to constitute a cause of action.


Mallinckrodt bases this Demurrer on this Notice of Demurrer, the following Demurrer to the Complaint and each of its counts, the supporting Memorandum in support of Demurrer and Motion to Strike (filed contemporaneously in a separate document given that the memorandum supports both a demurrer and a motion to strike), the supporting Declaration of Eric Shapland, all records and pleadings on file with the Court in this action, all other matters of which judicial notice may be taken, including matters subject to Mallinckrodt's contemporaneously filed Request for Judicial Notice in support of Demurrer and Motion to Strike, and all further evidence and argument that may be presented in Reply to any Opposition to this Demurrer at or before the hearing on this Demurrer.

Dated: May 28, 2020

Respectfully Submitted,

ARNOLD & PORTER KAYE SCHOLER LLP

By:


D. Eric Shapland

*Attorneys for Defendant
Mallinckrodt ARD LLC and
Mallinckrodt plc*

GENERAL DEMURRER TO PLAINTIFF'S COMPLAINT

1. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), defendant Mallinckrodt ARD LLC and Mallinckrodt plc ("Mallinckrodt") generally demurs to plaintiff Health Care Service Corporation's ("HCSC") Complaint ("Cmplt."), in its entirety, on the ground that the Complaint fails to state facts sufficient to constitute a cause of action.

DEMURRER TO PLAINTIFF'S COUNT ONE

NEW JERSEY RICO ACT

2. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the first cause of action (violation of the New Jersey RICO Act) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action because the conduct on which it is based—Mallinckrodt's provision of, or support for, copay assistance programs—neither constitutes a commercial bribe (as HCSC's members do not owe it a fiduciary duty) nor involves any actionable fraud (because any allegation that certifications of compliance with law were false because of associated violations of the federal Anti-Kickback Statute are time barred under the N.J. RICO Act's limitation period).

DEMURRER TO PLAINTIFF'S COUNT TWO

CONSPIRACY TO VIOLATE NEW JERSEY RICO ACT

3. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the second cause of action (conspiracy to violate New Jersey RICO Act) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action because the conduct on which it is based—Mallinckrodt's provision of, or support for, copay assistance programs—neither constitutes a commercial bribe (as HCSC's members do not owe it a fiduciary duty) nor involves any actionable fraud (because any allegation that certifications of compliance with law were false because of associated violations of the federal Anti-Kickback Statute are time barred under the N.J. RICO Act's limitation period).

DEMURRER TO PLAINTIFF'S COUNT THREE

MONOPOLIZATION UNDER 28 STATES' LAWS

4. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the third cause of action (unlawful monopolization under 28 states' antitrust laws) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action because:

- (a) HCSC's allegations regarding the distribution of H.P. Acthar[®] Gel ("Acthar") (Cmplt. ¶¶ 11, 76-85) address presumptively procompetitive conduct, and HCSC makes no factual allegation that the form of distribution harms competition; and
- (b) HCSC's allegations regarding Mallinckrodt's predecessor in interest Questcor Pharmaceuticals, Inc.'s ("Questcor") acquisition of rights to Synacthen Depot ("Synacthen") (*id.* ¶¶ 15, 162-76) fail to state a claim on three independent grounds: (i) HCSC's "ACTH-only" market improperly excludes non-ACTH economic substitutes for Acthar; (ii) HCSC fails to allege facts connecting the acquisition to the current price of Acthar; (iii) HCSC's claims are barred by the statutes of limitations or other legal bars applicable to the 28 states' antitrust laws invoked under this Count.

DEMURRER TO PLAINTIFF'S COUNT FOUR

UNREASONABLE RESTRAINT OF TRADE UNDER 31 STATES' LAWS

5. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the fourth cause of action (unreasonable restraint of trade under 31 states' antitrust laws) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action because:

- (a) HCSC's allegations regarding the distribution of Acthar (*id.* ¶¶ 11, 76-85) address presumptively procompetitive conduct, and HCSC makes no factual allegation that the form of distribution harms competition; and
- (b) HCSC's allegations regarding Questcor's acquisition of rights to Synacthen (*id.* ¶¶ 15, 162-76) fail to state a claim on two independent grounds: (i) HCSC's "ACTH-only" market improperly excludes non-ACTH economic substitutes for Acthar; (ii)

1 HCSC fails to allege facts connecting the acquisition to the current price of Acthar;
 2 and (iii) HCSC's claims are barred by the statutes of limitations or other legal bars
 3 applicable to the 31 states' antitrust laws invoked under this Count.

4 **DEMURRER TO PLAINTIFF'S COUNT FIVE**

5 **UNFAIR AND DECEPTIVE PRACTICES UNDER 34 STATES' LAWS**

6 6. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt
 7 generally demurs to the fifth cause of action (violation unfair and deceptive trade practices acts of
 8 34 states) on the ground that the Complaint fails to state facts sufficient to constitute a cause of
 9 action because:

- 10 (a) HCSC's allegations regarding the distribution of Acthar (*id.* ¶¶ 11, 76-85) address
 11 presumptively procompetitive conduct, and HCSC makes no factual allegation that
 12 the form of distribution harms competition;
- 13 (b) HCSC's allegation that Mallinckrodt has improperly funded programs assisting
 14 patients with co-payments that must be made to obtain insurance coverage for
 15 medically necessary prescriptions (*id.* ¶¶ 12, 89-120) involved no actionable and
 16 unlawful, misleading or fraudulent conduct because (i) they involve no commercial
 17 bribes and (ii) any alleged violation of the federal Anti-Kickback statute is barred by
 18 the statutes of limitations or other legal bars applicable to the 34 states' unfair and
 19 deceptive practices acts invoked under this Count;
- 20 (c) HCSC's conclusion that payments to doctors as compensation for research or
 21 speaking engagements were thinly disguised bribes (*id.* ¶¶ 14, 149-61) fails to support
 22 the Count for two independent reasons (i) it does not rely on facts making that
 23 conclusion plausible, and (ii) it does not rely on facts connecting the conduct to
 24 HCSC's alleged injury given HCSC's review of all Acthar prescriptions for medical
 25 necessity and the public disclosure of the payments to doctors; and
- 26 (d) HCSC allegations that Questcor promoted Acthar for an off-label dosing regimen to
 27 treat multiple sclerosis ("MS") (*id.* ¶¶ 13, 121-48) fail to plead any false statement
 28 and lack any reasonable specificity with respect to any alleged statements or reliance.

DEMURRER TO PLAINTIFF'S COUNT SIX

COMMON LAW FRAUD

7. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the sixth cause of action (fraud) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action because:

- (a) HCSC's allegations that Mallinckrodt certified compliance with law but improperly funded programs assisting patients with co-payments that must be made to obtain insurance coverage for medically necessary prescriptions (*id.* ¶¶ 12, 89-120) involved no actionable fraudulent conduct because (i) the programs involve no commercial bribes and (ii) any alleged violation of the federal Anti-Kickback statute is barred by the statute of limitations for common law fraud; and
- (b) HCSC's allegations that Mallinckrodt certified compliance with law and conclusion that payments to doctors as compensation for research or speaking engagements were thinly disguised bribes (*id.* ¶¶ 14, 149-61) fail to support the Count for two independent reasons (i) it does not rely on facts making that conclusion plausible, and (ii) it does not rely on facts connecting the conduct to HCSC's alleged injury given HCSC's review of all Acthar prescriptions for medical necessity and the public disclosure of the payments to doctors.

DEMURRER TO PLAINTIFF'S COUNT SEVEN

VIOLATION OF INSURANCE FRAUD STATUTES OF 40 STATES

8. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the seventh cause of action (violation of 40 states' insurance fraud statutes) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action because the statutes do not provide private rights of action and are subject to other legal bars to recovery, and the additional alternative reason that HCSC has failed to plead actionable misconduct under those statutes because:

- (a) HCSC's allegations that Mallinckrodt certified compliance with law but improperly funded programs assisting patients with co-payments that must be made to obtain

insurance coverage for medically necessary prescriptions (*id.* ¶¶ 12, 89-120) involved no actionable fraudulent conduct because (i) the programs involve no commercial bribes and (ii) any alleged violation of the federal Anti-Kickback statute is barred by the statutes of limitations or other legal bars applicable to the 4 of the 40 states' insurance fraud statutes that do provide private remedies; and

- (b) HCSC's allegations that Mallinckrodt certified compliance with law and conclusion that payments to doctors as compensation for research or speaking engagements were thinly disguised bribes (*id.* ¶¶ 14, 149-61) fail to support the Count for two independent reasons (i) it does not rely on facts making that conclusion plausible, and (ii) it does not rely on facts connecting the conduct to HCSC's alleged injury given HCSC's review of all Acthar prescriptions for medical necessity and the public disclosure of the payments to doctors.

DEMURRER TO PLAINTIFF'S COUNT EIGHT

TORTIOUS INTERFERENCE WITH CONTRACTUAL RELATIONS

9. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the eighth cause of action (tortious interference with contractual relations) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action because, by copay assistance, HCSC's members do not breach their contractual obligations to HCSC.

DEMURRER TO PLAINTIFF'S COUNT NINE

UNJUST ENRICHMENT

10. Pursuant to Code of Civil Procedure §§ 430.10(e) and 430.50(a), Mallinckrodt generally demurs to the ninth cause of action (unjust enrichment) on the ground that the Complaint fails to state facts sufficient to constitute a cause of action.

PRAYER

Mallinckrodt prays for the following relief:

1. That HCSC take nothing by reason of its Complaint;
2. That the demurrers to the Complaint and to each of the specific causes of action set forth therein be sustained;

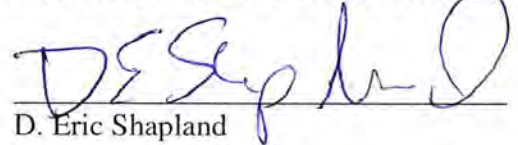
3. That HCSC's Complaint be dismissed without leave to amend;
4. That Mallinckrodt be awarded its costs; and
5. For any other or further relief as this Court deems just and proper.

Dated: May 20, 2020

Respectfully Submitted,

ARNOLD & PORTER KAYE SCHOLER LLP

By:


D. Eric Shapland

*Attorneys for Defendant
Mallinckrodt ARD LLC and
Mallinckrodt plc*

DECLARATION OF ERIC SHAPLAND

I, D. Eric Shapland, hereby declare as follows:

1. I am an attorney licensed to practice law in the State of California, and I am of counsel with the law firm of Arnold & Porter Kaye Scholer LLP, counsel of record for Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (the "Defendant Mallinckrodt Entities") in this action. I am a member of good standing of the State Bar of California.

2. I make this declaration upon personal knowledge of the facts set forth herein, and, if called upon to testify, could and would testify competently to such facts if called to do so.

3. Pursuant to Code of Civil Procedure §§ 430.41 and 435.5, on April 16 and 28, 2020, I met via telephone with Matthew Weiler, counsel for plaintiff Health Care Service Corp. to discuss the grounds on which the Defendant Mallinckrodt Entities rest this Demurrer (as well as the contemporaneously filed Motion to Strike) to attempt in good faith to resolve the matter. The parties did not reach an agreement resolving the objections raised.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. This declaration was executed this 20th day of May, 2020, in Los Angeles, California.

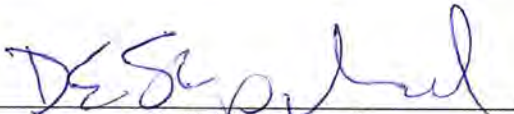

D. Eric Shapland

EXHIBIT 27

ARNOLD & PORTER KAYE SCHOLER LLP

Matthew M. Wolf (*PHV* to be filed)

Laura S. Shores (*PHV* to be filed)

Sonia Kuester Pfaffenroth (SBN 223984)

Michael B. Bernstein (*PHV* to be filed)

Adam M. Pergament (SBN 267557)

601 Massachusetts Avenue, N.W.

Washington, D.C. 20001-3743

Telephone: (202) 942-5000

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D. Eric Shapland (SBN 193853)

777 South Figueroa Street, 44th Floor

Los Angeles, CA 90017-5844

Telephone: (213) 243-4000

Facsimile: (213) 243-4199

eric.shapland@arnoldporter.com

Attorneys for Defendants

Mallinckrodt ARD LLC and Mallinckrodt plc

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**DEFENDANT MALLINCKRODT
ENTITIES' NOTICE OF MOTION
AND MOTION TO STRIKE
ALLEGATIONS FROM PLAINTIFF
HCSC'S COMPLAINT; SHAPLAND
DECLARATION**

Date: Aug. 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Reservation No. R-2179416

Action Filed: February 27, 2020

ENDORSED
FILED
ALAMEDA COUNTY

MAY 28 2020

CLERK OF THE SUPERIOR COURT
By *Jessica Herron*
Deputy

NOTICE OF MOTION AND MOTION

TO THE COURT, ALL INTERESTED PARTIES, AND COUNSEL OF RECORD:

PLEASE TAKE NOTICE that, on August 5, 2020 at 3:00 pm, or as soon thereafter as the matter may be heard, in Department 19 of this Court's Complex Division, located at 1221 Oak Street, 3rd Floor, Oakland, CA 94612, defendants Mallinckrodt ARD LLC and Mallinckrodt plc ("Mallinckrodt") will and hereby do move to strike allegations from plaintiff Health Care Service Corporation's ("HCSC") Complaint, pursuant to Code of Civil Procedure §§ 436(a).

Specifically, Mallinckrodt requests that the Court strike the following allegations from the Complaint:

Allegations Regarding Distribution of H.P. Acthar® Gel ("Acthar"):

- Complaint ¶¶ 11, 76-85: HCSC's allegations that entirely lawful enhancements to the distribution system for Acthar are among the five types of allegedly improper conduct by which Mallinckrodt was able to inflate Acthar's price.

Allegations Regarding Copay Assistance Programs:

- Complaint ¶¶ 12, 89-120: HCSC's allegations that Mallinckrodt's copay assistance programs and its contributions to copay assistance funds of an independent charity Chronic Disease Fund ("CDF") are among the five types of allegedly improper and actionable conduct by which Mallinckrodt was able to inflate the price of Acthar® Gel ("Acthar").
- Complaint ¶ 323, lns. 5-6: HCSC's allegations that Mallinckrodt's copay assistance programs constituted a violation of state bribery statutes and thus is "racketeering" activity under New Jersey's RICO Act.
- Complaint ¶¶ 273-75: HCSC's allegations that contributions to CDF copay assistance funds involved actionable fraud or breach of its members' contractual obligations to HCSC.
- Complaint ¶ 281, ln. 22: HCSC's allegation that Mallinckrodt's copay assistance programs involve any actionable fraud.

Allegations Regarding Payments to Doctors

- Complaint ¶¶ 14, 149-61: HCSC’s allegations regarding Mallinckrodt’s investments in medical research and education and conclusions that those investments were “thinly disguised” bribes to doctors in exchange for writing Acthar prescriptions causing harm to HCSC.
- Complaint ¶ 259: HCSC’s conclusion that Mallinckrodt made payments to doctors to induce them to make false certifications.
- Complaint ¶¶ 272-73: HCSC’s conclusions that Mallinckrodt made payments to doctors in exchange for increased rates of prescriptions.
- Complaint ¶ 181, Ins. 21-22: HCSC’s conclusion that Mallinckrodt made payments to doctors in exchange for increased rates of prescriptions.

Allegations Regarding Supposed False, Off-Label Promotion

- Complaint ¶¶ 13, 121-48: HCSC’s allegations that Mallinckrodt promoted Acthar for off-label uses.

Allegations Regarding the Synacthen Depot (“Synacthen”) Acquisition

- Complaint ¶¶ 15, 162-76, 244-47, 249-53: HCSC’s allegations that the 2013 acquisition of rights to Synacthen Depot (“Synacthen”) by Mallinckrodt (through its predecessor in interest Questcor Pharmaceuticals, Inc.) was an act of illegal monopolization or otherwise an unreasonable restraint of trade for which HCSC may seek relief under 31 states’ antitrust acts.
- Complaint ¶ 200: HCSC’s allegation that the relevant period on its antitrust claims begins in 2011.
- Complaint ¶ 203: HCSC’s allegation that competition with Acthar would have begun prior to 2014 but for the acquisition.

Allegations Regarding Inadmissible Settlements

- Complaint ¶ 161: HCSC’s allegation about a September 4, 2019 settlement agreement between Mallinckrodt and the United States Department of Justice.

- Complaint ¶ 175: HCSC's allegation about a January 18, 2017 settlement between Mallinckrodt and the Federal Trade Commission.

Allegations Invoking Inapplicable States' Laws

- Complaint ¶ 245: Reference to any of the 28 state antitrust acts that HCSC invokes in support of Count III and that the Court determines to be subject to a legal bar.
- Complaint ¶ 253: Reference to any of the 31 state antitrust acts that HCSC invokes in support of Count IV and that the Court determines to be subject to a legal bar.
- Complaint ¶ 245: Reference to any of the 34 state unfair and deceptive trade practices acts that HCSC invokes in support of Count V and that the Court determines to be subject to a legal bar.
- Complaint ¶ 280: Reference to any of the 40 state insurance fraud statutes that HCSC invokes in support of Count VII and that the Court determines to be subject to a legal bar.


Mallinckrodt bases its motion on this Notice of Motion and Motion, the supporting Memorandum in support of Demurrer and Motion to Strike (filed contemporaneously in a separate document given that the memorandum supports both a demurrer and a motion to strike), the supporting Declaration of Eric Shapland, all records and pleadings on file with the Court in this action, all other matters of which judicial notice may be taken, including matters subject to Mallinckrodt's contemporaneously filed Request for Judicial Notice in support of Demurrer and Motion to Strike, and all further evidence and argument that may be presented in Reply to any Opposition to this Motion at or before the hearing on this Motion.

Dated: May 28, 2020

Respectfully Submitted,

ARNOLD & PORTER KAYE SCHOLER LLP

By:


D. Eric Shapland

*Attorneys for Defendant
Mallinckrodt ARD LLC and
Mallinckrodt plc*

DECLARATION OF ERIC SHAPLAND

I, D. Eric Shapland, hereby declare as follows:

1. I am an attorney licensed to practice law in the State of California, and I am of counsel with the law firm of Arnold & Porter Kaye Scholer LLP, counsel of record for Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (the "Defendant Mallinckrodt Entities") in this action. I am a member of good standing of the State Bar of California.

1. I make this declaration upon personal knowledge of the facts set forth herein, and, if called upon to testify, could and would testify competently to such facts if called to do so.

2. Pursuant to Code of Civil Procedure §§ 430.41 and 435.5, on April 16 and 28, 2020, I met via telephone with Matthew Weiler, counsel for plaintiff Health Care Service Corp. to discuss the grounds on which the Defendant Mallinckrodt Entities rest this Motion to Strike (as well as the contemporaneously filed Demurrer to the Complaint) to attempt in good faith to resolve the matter. The parties did not reach an agreement resolving the objections raised.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. This declaration was executed this 20th day of May, 2020, in Los Angeles, California.

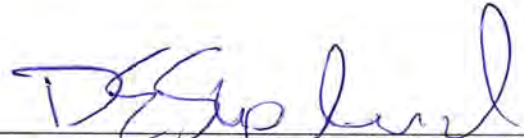

D. Eric Shapland

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MEMORANDUM

Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (collectively “Mallinckrodt”) respectfully submit this memorandum in support of their demurrer to, and motion to strike allegations from, the Complaint (“Cmplt.”) of plaintiff Health Care Service Corporation (“HCSC”).

I. INTRODUCTION

HCSC, one of the nation’s largest and most sophisticated healthcare insurers, claims that for the last eight years it paid too much for too many prescriptions for Acthar® Gel (“Acthar”) (Cmplt. ¶ 16), Mallinckrodt’s injectable specialty biopharmaceutical product with a long history, complex manufacturing process, and FDA approval for 19 serious and hard-to-treat medical conditions (*id.* ¶¶ 56-57, 62-64 & Request for Judicial Notice (“RJN”) Ex. G). HCSC would attribute the price for and volume of its purchases to alleged illegal monopoly, bribery, and fraud by Mallinckrodt’s predecessor in interest Questcor Pharmaceuticals, Inc. (“Questcor”) and later Mallinckrodt, which acquired Questcor in 2014. (*Id.* ¶¶ 4, 10-15.) HCSC concedes, however, that it contemporaneously reviewed for medical necessity each Acthar prescription that it covered. (*Id.* ¶ 271.) And while HCSC labels a 2007 price increase for Acthar as “price gouging” (*id.* ¶ 1), HCSC admits that Questcor made that price adjustment to pull Acthar out of a “financial sinkhole” and “save” the therapeutic after purchasing its rights in 2001. (*Id.* ¶¶ 7-9.) Since 2007, the price of Acthar has risen at only five percent per year not counting inflation. (*Id.* ¶ 8.)

Saving Acthar, which was critically important for the small number of patients who need it (*id.* ¶¶ 6, 61, 67), was not just a matter of pricing. Questcor made significant investments in medical research into the product’s safety and efficacy for new indications—investments that have only grown under Mallinckrodt’s ownership—as well as education for prescribers about Acthar’s FDA-approved indications, so the therapy is appropriately prescribed to the patients for whom it is a suitable treatment. (*See id.* ¶¶ 14, 148, 151.) Questcor also improved the distribution system for Acthar—which requires special handling and must be refrigerated—by shifting to the specialty-pharmaceutical distribution model, which provides greater care, speed, and expertise in ensuring this perishable specialty therapeutic is efficiently delivered to patients who need it urgently. (*See id.* ¶¶ 57, 76-79, 83.) As is typical for specialty pharmaceuticals, Questcor also established a patient

support program or “hub” that, as HCSC admits, helps patients submit insurance claims, appeal denials of coverage, secure financial assistance with co-payment obligations, coordinate home delivery, and provide injection training and support. (*Id.* ¶¶ 80-82, 89-115.)

HCSC’s effort to recast the resulting turnaround of Acthar as the result of illegal monopoly, bribery, and fraud is a disingenuous litigation tactic, by which it seeks to retroactively renegotiate the price it paid over the last eight years for medically necessary prescriptions. A few other third-party payers (“TPPs”) have tried to do the same by filing similar cases in other courts, which most often have substantially narrowed or dismissed the actions on the pleadings.¹ Once stripped of HCSC’s incendiary labels, none of the five categories of alleged misconduct supports the Complaint’s nine counts for relief under forty states’ laws:

(1) Enhanced Distribution and Patient Support. HCSC first complains about Questcor’s changes to Acthar’s distribution model by using phrases like “vertical integration,” “exclusive distribution,” or “consolidation into a single distribution channel” (*id.* ¶¶ 11, 76-85) as if they were labels for anticompetitive conduct. But all states whose antitrust laws HCSC invokes adhere to *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36 (1977), which holds that exclusive distribution agreements and other “vertical restraints” are *presumptively procompetitive* because they allow for just the kind of improvements in distribution that Questcor achieved for Acthar. HCSC’s allegation that the distribution agreement helped Questcor “maintain control over pricing pressures” (*id.* ¶ 11) both (a) makes no economic sense, because it already held that power as

¹ *MSP Recovery Claims, Series LLC, et al. v. Mallinckrodt ARD Inc.*, No. 3:20-cv-50056 (N.D. Ill. Mar. 23, 2020) (dismissing, with leave to amend, complaint for failure to plead standing); *Humana Inc. v. Mallinckrodt ARD LLC*, No. CV 19-06926 (C.D. Cal. Mar. 9, 2020) (“*Humana Order*”) (RJN Ex. J) (dismissing, with leave to amend, antitrust and tortious interference—but allowing RICO, consumer protection, and common law—claims); *Acument Global Techs., Inc. v. Mallinckrodt ARD, Inc.*, No. CT-2275-19 (Cir. Ct. Shelby Cty. Tenn. Feb. 21, 2020) (dismissing fraud and consumer protection, but allowing antitrust and unjust enrichment, claims); *Wash. Cty. Bd. of Educ. v. Mallinckrodt ARD, Inc.*, _ F. Supp. 3d _, No. CV JKB-19-1854, 2020 WL 43016 (D. Md. Jan. 3, 2020) (dismissing action of fraud and consumer-protection claims); *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019) (dismissing RICO and common-law, but allowing antitrust, claims); *but see Steamfitters Local Union No. 420 v. Mallinckrodt ARD, LLC*, No. 19-cv-03047 (E.D. Pa. Dec. 19, 2019) (denying, without an opinion, motion to dismiss RICO, consumer-protection, and common-law claims); *Int’l Union of Oper. Eng’rs Local 542 v. Mallinckrodt ARD, LLC*, No. 2018-14059 (Pa. Commw. Ct., Mont. Cty. Jan. 8, 2019) (same).

Acthar's only manufacturer and (b) contradicts well-established law. That contradiction leaves HCSC without allegations of harm to competition required to state a claim under any state's antitrust laws, and thus "necessarily implies that the conduct is not 'unfair' toward consumers," *Chavez v. Whirlpool Corp.*, 93 Cal. App. 4th 363, 375 (2001).

(2) **Co-pay Assistance.** HCSC also complains that Mallinckrodt has improperly funded programs assisting patients with co-payments that must be made to obtain insurance coverage for medically necessary prescriptions. (*Id.* ¶¶ 12, 89-120.) Mallinckrodt is committed to removing barriers to patient access to its products and has offered robust patient assistance programs as permitted by law. Interested in keeping those barriers, HCSC accuses patients who receive co-pay assistance of taking bribes or breaching their contractual obligations to HCSC (*id.* ¶¶ 12, 223, 288), accusations that were rejected on the pleadings by another court in an identical challenge to Questcor and Mallinckrodt's programs, *Humana* Order at 27-28 (rejecting bribery theory) & 34 (rejecting tortious interference theory). HCSC also alleges that Questcor's donations between 2010 and 2014 to charitable funds operated by the Chronic Disease Fund ("CDF") violated 2005 regulatory guidance on federal law applicable to Medicare Part D programs because the funds covered only Acthar prescriptions. (*Id.* ¶¶ 95-119.) HCSC, however, was put on constructive notice of its claims regarding CDF by as early as 2013, when prominent media outlets, such as the *New York Times*, reported on this conduct and specifically Questcor's contributions to Acthar-only funds at CDF. HCSC does not allege that Questcor continued to contribute to CDF funds after supplemental regulatory guidance in 2014 addressed the issue of single-drug funds. (*Id.* ¶ 120.) As result, all claims based on CDF contributions are time barred.

(3) **Payments to Doctors.** With sweeping and general allegations, HCSC labels Questcor and Mallinckrodt's investments in medical research and healthcare-provider education as "thinly disguised" bribes paid to doctors in exchange for writing Acthar prescriptions. (*Id.* ¶¶ 14, 149-61.) But HCSC admits that the amount of compensation for this work was within the range of the "industry standard." (*Id.* ¶ 153). And HCSC pleads no other facts supporting its mischaracterization. In addition, HCSC's conclusory allegation that it would not have covered Acthar prescriptions had it known of these payments is contradicted by its allegations elsewhere

1 that compensation provided to doctors has been publicly disclosed since 2013 (*id.* ¶ 158) and that
 2 HCSC reviewed for medical necessity each claim for an Acthar prescription (*id.* ¶ 271). And HCSC
 3 fails to identify a single doctor who wrote a prescription as a result of an illegal payment. These
 4 failures compel dismissal of HCSC’s claims regarding purported bribes to doctors.

5 **(4) Off-Label Promotion.** HCSC alleges that Questcor promoted Acthar for an off-label
 6 dosing regimen to treat multiple sclerosis (“MS”). (*Id.* ¶¶ 13, 121-48.) HCSC dedicates several
 7 paragraphs to outlining at a generalized level allegations of internal discussions about the
 8 development of marketing strategy for Acthar. But nowhere does HCSC allege with particularity a
 9 single instance of any actual off-label promotion of Acthar by anyone at Questcor or Mallinckrodt
 10 to a single doctor—let alone to a doctor who wrote a prescription for such off-label use for an HCSC
 11 beneficiary. HCSC’s failure to plead fraud and reliance with particularity mandates dismissal of
 12 the fraud-based claims. *See Wash. Cty.*, 2020 WL 43016, at *11.

13 **(5) The Synacthen Transaction.** HCSC alleges that Questcor violated 32 states’
 14 antitrust laws when it acquired, in June of 2013, the development rights to the synthetic ACTH drug
 15 Synacthen Depot (“Synacthen”), which HCSC alleges would have served as a price-disciplining
 16 alternative for Acthar but-for the acquisition. (*Id.* ¶¶ 15, 162-76). These claims fail for multiple
 17 reasons. *First*, HCSC rests its claims on a proposed relevant antitrust market in which only Acthar
 18 competes (*id.* ¶ 183), even as HCSC admits that Acthar faces competition from other
 19 pharmaceuticals (*id.* ¶¶ 6, 58, 89, 166-68). The admission is fatal to the claims, *Humana* Order at
 20 5-13 (dismissing with leave to amend similar claims based on Acthar-only market). *Second*, HCSC
 21 has not sufficiently alleged actual injury from this transaction or a proper form of relief. According
 22 to HCSC, but for the 2013 acquisition, “competition to Acthar would have begun prior to 2014, and
 23 would have included Synacthen.” (*Id.* ¶ 203.) But Synacthen is a different drug that is not FDA-
 24 approved for sale in the United States (*id.* ¶ 15), and approval depends on the outcome of lengthy
 25 and uncertain clinical trials and FDA evaluation. HCSC admits that Mallinckrodt sublicensed its
 26 rights to Synacthen almost three years ago (*id.* ¶ 176); HCSC does not plead that the sublicensee
 27 has obtained FDA approval; and HCSC pleads nothing about any timetable for or nature of such
 28 approval. *Finally*, waiting almost seven years to sue, HCSC blew the 32 states’ time bar.

For these and other reasons stated below, the Complaint fails to state a claim for relief, and Mallinckrodt respectfully urges the Court to dismiss this action in its entirety. Alternatively, the Court should substantially narrow the scope of this kitchen-sink action by dismissing specific counts and/or striking from the Complaint, as substantively defective and irrelevant matter, categories of alleged misconduct that do not support any claim for relief as well as requests for damages that are unsupported by any claim stated.

II. THE COMPLAINT

A. Acthar and Its Manufacture, Promotion, Distribution, and Sale Before Questcor Acquired Its Rights.

Acthar's active ingredient is an adrenocorticotrophic hormone analogue ("ACTH") that is extracted from pig pituitary glands. (Cmplt. ¶¶ 5, 56-57.) Once extracted, refined, and purified through a process protected by trade secrets, the ACTH is combined with a gel to extend its release into, and therapeutic effects on, the body. (*Id.* ¶ 57.) The gel requires special handling, including refrigeration until use, which occurs through a repository injection. (*Id.*)

The FDA approved Acthar first in 1952 for numerous conditions causing inflammation (*id.* ¶¶ 5, 56, 185) and later in 1979 for multiple sclerosis ("MS") (*id.* ¶ 60). By the 1990s, low-cost synthetic steroidal and non-steroidal anti-inflammatory drugs were available, competing with Acthar for many of the FDA-approved indications for which there are large patient populations. (*Id.* ¶¶ 6, 58, 66-68). By this time, doctors regularly prescribed Acthar for only a few uses. One was an "off-label" use as the standard of care to treat approximately 1,200 annual cases of infantile spasms ("IS") (*id.* ¶¶ 67-68), a rare but catastrophic syndrome affecting infants up to two years of age. Acthar was also prescribed as a last-resort treatment for a small population of patients suffering from "acute exacerbations" of multiple sclerosis ("MS"), which is a disease state marked by a "worsening of existing MS symptoms or the onset of other MS symptoms," or other rare conditions, when multiple other treatment options, including steroids, have failed. (*Id.* ¶ 6, 61.)

As HCSC admits, by 2001, high production costs and low sales volume made Acthar "unprofitable for its manufacturer" which "considered stopping production" (*id.* ¶ 7), and Acthar was a "nearly extinct, financial sinkhole," (*id.* ¶ 9). But then, "the drug was saved in 2001, when . . . Questcor purchased the right to produce this unprofitable . . . drug." (*Id.* ¶ 7.)

B. Questcor's Acquisition and Repositioning of Acthar

HCSC uses 2001—the point in time at which Acthar was at its lowest, when it was a “financial sinkhole”—as the starting point for its allegation of “a run of outrageous price increases” for Acthar. (Cmplt. ¶¶ 7-9.) But a new pricing strategy and repositioning is exactly what Acthar needed to remain on the market and available to the patients who need it. In our economic system, pricing a product according to its value “is not only not unlawful; it is an important element of the free-market system [It] is what attracts ‘business acumen’ in the first place; it induces risk taking that produces innovation and economic growth.” *Verizon Comm’n v. Law Offices of Curtis Trinko*, 540 U.S. 398, 407 (2004); *Freeman v. San Diego Ass’n of Realtors*, 77 Cal. App. 4th 171, 200 (1999). And in 2007, Questcor implemented a common pricing strategy for important drugs with small patient populations (an orphan pricing strategy), under which it raised Acthar’s price to \$23,269 per vial. (Cmplt. ¶ 8.) This adjustment occurred before any alleged unlawful conduct. Since 2007, the price of Acthar has risen at about five percent per year, not counting inflation. (*Id.*) HCSC makes no allegation that this adjusted price was out of line with the price other specialty pharmaceutical products that, like Acthar, are prescribed to treat small patient populations suffering from rare and/or difficult to treat conditions.

In addition to this 2007 price adjustment, Questcor made other changes to Acthar’s positioning in the market to improve the viability of the product. Questcor began the process of securing FDA approval to add IS to Acthar’s label, which would finally permit doctors to be appropriately educated about Acthar’s effectiveness for treating this rare disease. (RJN Ex. F.) Questcor also transitioned Acthar into a distribution system well-suited for specialty pharmaceuticals, one capable of handling “high-cost, high-complexity, and/or high-touch medication therapy for patients with complex disease states.” (Cmplt. ¶ 77.) Questcor retained CuraScript SD to distribute the medicine to multiple specialty pharmacies capable of carefully delivering Acthar to patients’ homes. (*Id.* ¶ 79.) Questcor also retained United BioSource Corporation (“UBC”) to design and administer “patient access centers,” such as the Acthar Support and Access Program (“ASAP”), to “assist patients and prescribers with navigating prescription drug coverage,” pharmacy options, and patient co-pay assistance programs, and to provide other patient

support services (including nurses to advise patients on administration and storage). (*Id.* ¶ 80.) And Questcor made significant investments in lawfully educating doctors to make them aware of Acthar as an option for appropriate patients suffering from its many FDA-approved indications, as well as researching into Acthar’s safety and efficacy for disease states where existing therapies are ineffective. (*Id.* ¶¶ 14, 147.)

In 2014, Mallinckrodt plc acquired Questcor, which became Defendant Mallinckrodt ARD LLC—the entity that continues to manufacture and sell Acthar. (*Id.* ¶¶ 9, 20, 24.) Today, in addition to remaining the standard of care for treating IS, Acthar provides relief from symptoms of acute exacerbations of MS; and it is a “last line” alternative when steroids and other therapies are not effective for treating various conditions such as rheumatoid arthritis (“RA”), Lupus, and nephrotic syndrome (“NS”), which affects the kidneys. (*Id.* ¶¶ 60, 62, 64, 185-86.)

C. HCSC and Its Purported Claims for Relief

HCSC offers Blue Cross Blue Shield plans in five states and other private plans around the country. (*Id.* ¶ 17.) It also contracts with the federal government to sponsor Medicare Part D prescription drug benefits and Part C Medicare Advantage Plans. (*Id.* ¶ 18.) HCSC alleges that it has spent over \$100 million on Acthar prescriptions since 2011. (*Id.* ¶ 85.) HCSC admits that, at all times relevant to its claims, it has had a prior authorization process in place to ensure the medical necessity of Acthar prescriptions before providing coverage. (*Id.* ¶ 259.)

HCSC alleges that Questcor and later Mallinckrodt were able to “inflate” the price of Acthar through five “types of related and improper conduct” (*Id.* ¶ 10): (1) structured distribution for Acthar (*id.* ¶¶ 11, 76-85); (2) co-pay assistance programs (*id.* ¶¶ 12, 89-120); (3) payments to doctors for research and education (*id.* ¶¶ 14, 149-61); (4) alleged false, off-label promotion (*id.* ¶¶ 13, 121-48); and (5) acquiring the rights to the synthetic ACTH product Synacthen (*id.* ¶¶ 15, 162-76). HCSC asserts nine separate counts under the laws of over forty different states (*id.* ¶¶ 216-96) and places at issue every Acthar prescriptions that it covered back to 2011. (*Id.* ¶ 297.)

III. THE LEGAL STANDARD

“A demurrer tests . . . whether [the complaint] states facts sufficient to constitute a cause of action upon which relief may be granted.” *Seidler v. Mun. Ct.*, 12 Cal. App. 4th 1229, 1233 (1993);

1 *see also Cal. Logistics, Inc. v. State of Cal.*, 161 Cal. App. 4th 242, 247 (2008); Civ. Proc. Code §
 2 430.10(e). In assessing the sufficiency of the complaint, “the trial court may consider all material
 3 facts pleaded in the complaint and those arising by reasonable implication therefrom,” *Young v.*
 4 *Gannon*, 97 Cal. App. 4th 209, 220 (2002), as well as all judicially noticeable facts, Civ. Proc. Code §
 5 430.30(a); *Blank v. Kirwan*, 39 Cal. 3d 311, 318 (1985). Factual allegations offered in
 6 support of a claim “must be plausible.” *Prakashpalan v. Engstrom, Lipscomb & Lack*, 223 Cal.
 7 App. 4th 1105, 1120 (2014). Trial courts “do not assume the truth of contentions, deductions, or
 8 conclusions of law.” *Cal. Logistics*, 161 Cal. App. 4th at 247; *see also Doe v. City of Los Angeles*,
 9 42 Cal. 4th 531, 550 n.5 (2007) (holding that “boilerplate allegations that defendants knew or were
 10 on notice of” illegal activity “would not be sufficient . . .”).

11 A motion to strike eliminates “irrelevant . . . matter inserted in any pleading.” Civ. Proc.
 12 Code § 436(a). “Irrelevant matter” includes (a) “an allegation that is not essential to the statement
 13 of a claim” and (b) “a demand for judgment requesting relief not supported by the allegations of the
 14 complaint.” Civ. Proc. Code § 431.10(b) & (c). Thus, “when a substantive defect is clear from the
 15 face of a complaint, . . . a defendant may attack that portion of the cause of action by filing a motion
 16 to strike.” *PH II, Inc. v. Super. Ct.*, 33 Cal. App. 4th 1680, 1682–83 (1995). A motion to strike is
 17 also “[t]he appropriate procedural device for challenging a portion of a cause of action seeking an
 18 improper remedy.” *Caliber Bodyworks, Inc. v. Super. Ct.*, 134 Cal. App. 4th 365, 385 (2005).

19 **IV. ARGUMENT²**

20 **A. Questcor’s Distribution Model Is Presumptively Lawful and HCSC Fails to Plead Otherwise.**

21 While HCSC includes Questcor’s exclusive distribution agreement with CuraScript SD and
 22 “integrated” patient services agreement with UBC on its list of “several types of related and
 23

24 ² Mallinckrodt organizes its argument around the five categories of alleged misconduct. In
 25 its Demurrer, Mallinckrodt identifies each of the arguments with which the Court must agree in
 26 order to dismiss each specific count and, in its Motion to Strike, Mallinckrodt identifies the
 27 allegations that should be stricken from the Complaint if the Court elects not to dismiss related
 28 counts. Count VII for alleged violations of 40 states’ insurance-fraud statutes is the only count that
 Mallinckrodt does not reference below. In California and 35 of the other states, the statutes do not
 provide a private right of action, and the other four have other legal bars or elements similar to
 common-law fraud and thus fail for the same reasons as Count V. (RJN Ex. K (Table of Out of
 State Authorities I).)

improper conduct” by Questcor and later Mallinckrodt (Cmplt. ¶¶ 10-11, 75, 79-80), HCSC does not expressly reference those agreements in support of any of its nine purported claims for relief. The omission is telling. As various admissions throughout the Complaint reveal, Questcor’s agreement with CuraScript ensures that Acthar is distributed to pharmacies for a modest, flat fee with the care required for a hard-to-manufacture and perishable therapeutic and the speed required to treat acute and otherwise urgent conditions. (*Id.* ¶¶ 57, 60, 67, 77, 83.) Similarly, Questcor’s patient support services agreement with UBC concededly helps patients “navigat[e] prescription drug coverage,” find co-payment and other financial assistance, and coordinate delivery. (*Id.* ¶¶ 57, 80-82.) Given the obvious benefits, it is unsurprising that HCSC’s Complaint fails to plead how these agreements give rise to a cause of action or support any of HCSC’s claims for relief.

The allegations fail to state a claim under any of the 32 states’ antitrust laws referenced in Counts III or IV. In contrast to certain agreements among competitors, agreements between companies that work together in the chain of distribution for a product—so-called vertical agreements—are not subject to any *per se* rule of illegality. As first recognized by the United States Supreme Court, vertical agreements have the potential to stimulate interbrand competition, which is competition between different manufacturers’ products, even as they diminish intrabrand competition, which is competition among distributors of the same manufacturer’s product. *GTE Sylvania*, 433 U.S. at 52, 54. Specifically, just as HCSC acknowledges Questcor to have done here, “manufacturers can use [vertical restraints] to induce” downstream sellers to, among other things, provide additional services that affect “a manufacturer’s goodwill and the competitiveness of his product,” and that “might not be provided by retailers in a purely competitive situation” due to “market imperfections such as the so-called ‘free rider’ effect.” *Id.* at 55. Because interbrand competition is the “primary purpose of the antitrust laws,” courts have held that these benefits will outweigh any impairment to intrabrand competition and leave the vertical restraint presumptively reasonable and lawful, unless the vertical restraint is shown to have a net harm to interbrand competition. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877, 890 (2007).³ *GTE*

³ *Republic Tobacco Co. v. North Atlantic Trading Co., Inc.*, 381 F.3d 717, 736 (7th Cir. 2004) (“vertical exclusive distributorships . . . are presumptively legal”); *Electronics Commc’ns Corp. v.*

1 *Sylvania* has been adopted by courts of California, *Bert G. Gianelli Distributing Co. v. Beck & Co.*,
 2 172 Cal. App. 3d 1020, 1045 (1985), and the other states on whose laws HCSC relies to challenge
 3 the distribution agreement, RJN Ex. L (Table of Out of State Authorities II).

4 HCSC has failed to meet its pleading burden under *GTE Sylvania*. To survive a demurrer
 5 “where an antitrust plaintiff alleges vertical restraints, facts must be pled showing ‘some
 6 anticompetitive effect in the larger, interbrand market.’” *Marsh v. Anesthesia Svcs. Medical Group,*
 7 *Inc.*, 200 Cal. App. 4th 480, 495 (2011) (sustaining demurrer for failure to state a claim for relief);
 8 *Exxon Corp. v. Superior Court*, 51 Cal. App. 4th 1672, 1680–81 (Cal. Ct. App. 1997) (“[A]n
 9 antitrust plaintiff attacking vertical restraints cannot make out a case unless the plaintiff can show
 10 some anticompetitive effect in the larger, interbrand market.”).⁴ In an attempt to meet this burden,
 11 HCSC alleges that the agreements “helped [Questcor] maintain control over pricing pressures.”
 12 (Cmplt. ¶ 11.) HCSC recognizes, however, that Questcor, and later Mallinckrodt, was the sole
 13 manufacturer of Acthar. (*Id.* ¶¶ 76, 182, 198, 243.) An exclusive distribution arrangement
 14 “provides no monopolistic benefit to [a monopolist] that it does not already enjoy” *E&L*
 15 *Consult., Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2nd Cir. 2006). And, while HCSC alleges
 16 that, under the agreement, Questcor exerted too much control over CuraScript because “CuraScript
 17 has no independent authority to set the price of Acthar,” “bears no risk from Acthar sales,” and “is
 18 completely controlled by Mallinckrodt and acts merely as its conduit” (Cmplt. ¶ 82-83), the net of
 19 HCSC’s allegations amount to nothing more than that CuraScript was a consignment seller, an
 20 arrangement which is not a restraint of trade under the antitrust laws, *Shasta Douglas Oil Co. v.*
 21 *Work*, 212 Cal. App. 2d 618, 622 (1963) (citing *United States v. General Electric Co.*, 272 U.S.
 22 476, 488 (1926)); *Wilke & Holzheiser, Inc. v. Dep’t of Alcoholic Beverage Control*, 65 Cal. 2d 349,

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 Toshiba Am. Consumer Prods., 129 F.3d 240, 245 (2d Cir. 1997) (same); *Crane & Shovel Sales*
Corp. v. Bucyrus-Eric Co., 854 F.2d 802, 807 (6th Cir. 1988) (same).

26 ⁴ See also *E&L Consult., Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 29 (2nd Cir. 2006) (affirming
 27 dismissal for failure to state a claim for relief); *E. Food Servs., Inc. v. Pontifical Catholic Univ. Servs.*
 28 *Ass’n, Inc.*, 357 F.3d 1, 8–9 (1st Cir. 2004) (same); *Elecs. Commc’ns Corp.*, 129 F.3d at 245 (same);
Crane & Shovel Sales Corp., 854 F.2d at 807 (same); *Rutman Wine Co. v. E&J Gallo Winery*, 829
 F.2d 729, 734-36 (9th Cir. 1987) (same).

366 n.13 (1966). HCSC’s allegations relating to CuraScript fall short of alleging a violation of any state antitrust laws at issue here.

Having failed to plead that Questcor’s control over its own pricing of its product constitutes a violation of state antitrust laws, it necessarily follows that HCSC cannot attempt to label the exclusive distribution agreement an “unfair” business practice in support of Count V. As the Court of Appeal recognized in *Chavez v. Whirlpool Corp.*, 93 Cal. App. 4th 363 (App. 2001):

If the same conduct is alleged to be both an antitrust violation and an “unfair” business act or practice for the same reason—because it unreasonably restrains competition and harms consumers—the determination that the conduct is not an unreasonable restraint of trade necessarily implies that the conduct is not ‘unfair’ toward consumers. . . . [C]onduct alleged to be “unfair” because it unreasonably restrains competition and harms consumers . . . is not “unfair” if the conduct is deemed reasonable and condoned under the antitrust laws.

Id. at 375. The procompetitive nature of the distribution agreement with CuraScript bars any suggestion that it is unfair.

For these reasons, HCSC’s challenge to Acthar’s structured distribution and patient support system must fail as a matter of law, no matter the legal theory HCSC pursues. No count can survive dismissal based on those allegations, which should be stricken from the Complaint.

B. HCSC’s Allegations Regarding Co-Pay Assistance Do Not State a Claim.

HCSC’s effort to transform Questcor’s and Mallinckrodt’s efforts to help ensure that patients have access to medically necessary prescriptions into illegal conduct is equally unavailing. The focus of HCSC’s allegations is a set of contributions that Questcor began making to CDF funds in 2010 to help patients suffering from acute exacerbations of MS and in 2011 to help patients suffering from exacerbations of rheumatoid arthritis and Lupus (Cmplt. ¶¶ 95-112). HCSC’s allegations also refer to Questcor’s alleged provision of assistance to certain patients for co-pays greater than \$150 and Mallinckrodt’s co-pay assistance programs after the 2014 acquisition of Questcor (*id.* ¶ 120). HCSC alleges that all of these co-pay assistance programs (1) violated state commercial bribery statutes (Counts I and II under the New Jersey RICO Act) (*id.* ¶¶ 12, 223); (2) violated the federal Anti-Kickback Statute (“AKS”), 42 U.S.C. § 1320a-7b(b) (Cmplt. ¶ 119), which does not provide a private right of action but allegedly renders false certifications of “compliance with law” that

Questcor made when HCSC was covering Acthar prescriptions for enrollees in its Medicare Advantage plans under Medicare Part D (Counts I, II, V and VI) (*id.* ¶¶ 219-220, 259, 267-70, 281); and (3) tortiously interfered with HCSC’s contracts with its members (Count VIII) (*id.* ¶¶ 256-90). None of these theories states a claim for relief; the respective counts in the Complaint should be dismissed for failure to state a claim or, at a minimum, the allegations regarding co-pay assistance programs should be stricken as “substantively defective” for the following three reasons.

1. Co-Pay Assistance Is Not a Commercial Bribe.

Contrary to HCSC’s contention, manufacturers do not make a commercial bribe by providing co-pay assistance for their pharmaceuticals.⁵ Commercial bribery statutes prohibit someone from accepting a benefit in exchange for violating a fiduciary duty. The only such statute that HCSC cites, for example, expressly provides: “A person commits a crime if he . . . accepts . . . any benefit as consideration for knowingly violating or agreeing to violate a *duty of fidelity*” N.J. Stat. § 2C:21-10 (emphasis added) (cited at Cmplt. ¶ 223). Other state statutes expressly prohibit conduct that constitutes such a breach. *E.g.*, Penal Code § 641.3 (paying another’s employee to induce him or her to provide an unauthorized benefit); Alaska Stat. §§ 11.46.660(a) & 11.46.670 (paying a physician to breach the physician’s duty to a patient).

Helping patients afford the medication their doctor has deemed medically appropriate and necessary by providing co-pay assistance involves no payment to a doctor to write the prescription, and patients do not breach any fiduciary duty to their insurers by accepting assistance because they do not owe such a duty to their insurers, as the few cases that have addressed HCSC’s unique contention have held. *Am. Fed’n of State, Cty. & Mun. Emp. Dist. Council 37 Health & Sec. Plan v. Bristol-Myers Squibb Co.*, 948 F. Supp. 2d 338, 355–62 (S.D.N.Y. 2013); *Humana* Order at 23. As the court in *Humana* reasoned when it rejected the same theory HCSC advances here—namely, that Questcor’s contributions to CDF were bribes: “The only parties that receive consideration as part of the co-pay funds are CDF and the patients Therefore, Plaintiff has not sufficiently alleged that the co-pay assistances funds constituted bribery.” *Id.*

⁵ Thus, at a minimum, HCSC’s allegation that co-pay assistance constitutes racketeering activity as a violation of state bribery statutes (Cmplt. ¶ 223:5-6) should be stricken from the Complaint.

2. **HCSC's Claims Based on the Allegation that CDF Co-Pay Assistance Funds Violated the Federal Anti-Kickback Statute Are Time Barred.**

HCSC's allegations that Questcor's contributions to certain CDF funds for "exacerbation" disease states violated the AKS are based on alleged conduct that has been in the public record since 2013 and that HCSC should have discovered (and was on constructive notice) at least six years ago. The statutes of limitations on HCSC's related claims began to run then. *See Bernson v. Browning-Ferris Indus.*, 7 Cal. 4th 926, 931 (1994). At five years or less,⁶ the relevant limitations periods all expired before HCSC filed this suit in 2020. Thus, HCSC's claims based on those allegations are time barred, and the claims should be dismissed or, at a minimum, the associated co-pay allegations stricken from the Complaint.⁷

Judicially noticeable facts and admissions in the Complaint make HCSC's longstanding constructive notice clear. CDF set these funds up specifically for patients who were enrollees in Medicare Part D plans. (Cmpl't. ¶¶ 98, 113.) The Department of Health and Human Services Office of Inspector General ("OIG") had issued guidance on how independent charity patient assistance programs ("PAPs") could comply with protections that are afforded to Medicare by the AKS, over and above those afforded by commercial bribery statutes. (RJN Ex. A (Publication of OIG Special Advisory Bulletin on Patient Assistance Programs ("PAPs") for Medicare Part D Enrollees ("2005 SAB"), 70 Fed. Reg. 70,623 (Nov. 22, 2005).) While the intent for the CDF funds was that they would be a manner to comply with the OIG's guidance, HCSC alleges that the CDF funds still violated the AKS because they did not comply with conditions on the OIG's approval of independent charity PAPs in the 2005 SAB.

⁶ Counts I and II are subject to a four-year limitation period. *Cetel v. Kirwan Fin. Grp., Inc.*, 460 F.3d 494, 510 (3d Cir. 2006) (N.J. RICO claims). Count V is subject to limitation periods that are four years in California, Bus. & Prof. Code § 17208 (Unfair Competition Law), and five years or less in all other relevant states except Maine, Michigan, Minnesota, North Dakota, Pennsylvania, and Vermont, which do not provide a claim for HCSC for other legal reasons, RJN Ex. M (Table of Out of State Authorities III). Count VI is subject to a three-year period. Civ. Proc. Code § 338(d).

⁷ When the complaint and judicially noticeable facts show that the statute of limitations prevents alleged misconduct from supporting a claim for relief, the claim can be dismissed by sustaining a demurrer, *see Barton v. New United Motor Mfg., Inc.*, 43 Cal. App. 4th 1200, 1210 (1996), unless other alleged misconduct supports the claim, in which case the allegations of misconduct can be stricken from the complaint, *PH II, Inc.*, 33 Cal. App. 4th at 1682–83.

1 The precise manner in which HCSC alleges the CDF funds violated the AKS has long been
 2 in the public record. HCSC alleges that, because the CDF funds were limited to patients with
 3 exacerbation disease states, only Acthar patients received assistance from the funds, and thus they
 4 served as an unlawful “conduit to pay patient co-pay subsidies for Acthar (but no other drug).”
 5 (Cmplt. ¶ 91; *id* ¶¶ 12, 96, 98, 102, 107-09, 110, 119.) Major U.S. news outlets reported on
 6 Questcor’s donations to CDF funds and the Acthar-only nature of those funds as early as 2013.
 7 (RJN Ex. C (Bill Alpert, *Too Close for Comfort*, Barron’s (Oct. 19, 2018)) & D (Andrew Pollack,
 8 *Drug Maker’s Donations to Co-Pay Charity Face Scrutiny*, N.Y. Times (Dec. 18, 2013)).) The
 9 *New York Times* reported, for example, that “although the [CDF] already offered support for
 10 multiple sclerosis, it started a new program for ‘acute exacerbations of M.S.,’ *which applies only to*
 11 *Acthar*.” (RJN Ex. D at 30 (emphasis added)). In addition, in May 2014, the OIG supplemented its
 12 guidance regarding PAPs “based on experience [it] gained” since issuing the 2005 SAB and
 13 specifically singled out the emergence of single-drug funds for costly, specialty pharmaceuticals
 14 and advised that they would be subject to scrutiny.⁸ (RJN Ex. B (Supplemental Special Advisory
 15 Bulletin: Independent Charity Patient Assistance Programs (“2014 SAB”)), 79 Fed. Reg. 31,120,
 16 31,120-22 (May 30, 2014).)

17 The public attention Questcor’s donations received clearly put HCSC on constructive notice
 18 of its co-pay assistance claims and the specific concerns it alleges today. *See Fox v. Ethicon Endo-*
 19 *Surgery, Inc.*, 35 Cal. 4th 797, 807-08 (2005) (holding that plaintiffs have constructive knowledge
 20 “if they have the opportunity to obtain knowledge from sources open to their investigation” (internal
 21 quotation marks omitted)); *McKelvey v. Boeing North Am., Inc.*, 74 Cal. App. 4th 151, 160, n.11

22 ⁸ HCSC makes no specific factual allegation that any contributions to CDF supposedly
 23 violating the AKS continued after the OIG issued the 2014 SAB. Rather, HCSC offers the generic
 24 allegation that, “[o]n information and belief, Mallinckrodt continued to pay or substantially
 25 subsidize required patient co-payments for Acthar after 2014 and continues to do so until today.”
 26 (Cmplt. ¶ 120.) Helping patients meet co-payment obligations for medically necessary prescriptions
 27 is not unlawful. HCSC’s allegation conspicuously fails to allege that, after 2014, Mallinckrodt
 28 continued making contributions to the CDF exacerbation funds for MS, Lupus and RA, or any
 single-drug fund for Medicare enrollees. Thus, the allegation is patently insufficient to plead
 violations after 2014. *Doe v. City of Los Angeles*, 42 Cal. 4th at 550 (holding insufficient
 “allegations of information and belief that merely asserted the facts so alleged without alleging . . .
 information that leads the plaintiff to believe that the allegations are true”).

(1999) (declining to toll statute of limitations because plaintiffs failed to explain “how they managed to ignore those ‘newspaper articles’” that provided an account of their alleged injury), *abrogation by statute on other grounds recognized by Lopez v. Sony Elecs., Inc.*, 5 Cal. 5th 627, 633 n.3 (2018); *Brandon G. v. Gray*, 111 Cal. App. 4th 29, 37 (2003).

3. Co-Pay Assistance Is Not a Tortious Interference with Contracts.

HCSC’s allegations regarding co-pay assistance fail to support any plausible claim that Mallinckrodt induced patients to breach any contractual obligation to their insurers—a breach which is an essential element of HCSC’s tortious interference theory, 2 Callmann on Unfair Competition, Trademarks and Monopolies § 9:9 (4th ed. June 2019). HCSC points to its form member contract, which allegedly contains a promise “that members will pay their share of the costs for prescription drugs.” (Cmplt. ¶ 286.) Incredibly, HCSC then alleges that its members breach that promise when accepting co-pay assistance to cover their share of the costs, and that HCSC was harmed by the breach because it would not have had to provide (medically necessary) healthcare to its members had they then not been able to meet their co-pays. (*Id.* ¶¶ 288-89.) Patients do *not*, however, breach their obligation to cover “their share of the costs” by accepting co-pay assistance to do so. As OIG has advised, “cost-sharing assistance furnished by a [patient assistance program], including a manufacturer [patient assistance program], will count toward a beneficiary’s [true out-of-pocket] expenditures, even if the [patient assistance program] does not comply with the fraud and abuse laws.” RJN Ex. A at 10.

As a result, HCSC’s tortious interference claim must be dismissed in its entirety, just as an identical claim regarding the same CDF funds was dismissed in *Humana*. *Humana* Order at 34; *see also Blue Cross of California Inc. v. Insys Therapeutics Inc.*, 390 F. Supp. 3d 996, 1009 (D. Az. 2019) (dismissing prescription TPP’s claim that manufacturer’s co-pay assistance program tortuously interfered with TPP’s contract).

C. HCSC Fails to Support Its Conclusory Allegations That Payments to Doctors Were Unlawful.

HCSC labels Questcor’s and Mallinckrodt’s investments in medical research and education as “thinly disguised bribes” to doctors in exchange for writing Acthar prescriptions (*id.* ¶¶ 14, 149-61) in an effort to state claims under 34 states’ unfair and deceptive trade practices acts (Count V)

(*id.* ¶ 259) and the doctrine of common-law fraud (Count VI) (*id.* ¶¶ 272-73) on the ground that certifications of “compliance with law” made to HCSC were therefore false. These allegations fail to support a claim for relief for two reasons.

(1) Alleging the legal conclusion of bribery is insufficient to state a claim, *Doe*, 42 Cal. 4th at 551 n.5, and HCSC fails to allege “specific facts” to make that conclusion plausible, as it must under the applicable pleading standard, *Prakashpalan*, 223 Cal. App. 4th at 1120. A pharmaceutical company can pay doctors to serve as speakers or researchers for its products, and the amount of those payments here was within the “industry standard,” as HCSC admits (Cmplt. ¶¶ 14, 153). The fact of these payments does not make HCSC’s conclusion plausible. *See Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014) (“When considering plausibility, courts must also consider an ‘obvious alternative explanation’ for [a] defendant’s behavior.”) (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 682 (2009))).

HCSC’s reference to a settlement agreement between Mallinckrodt and the United States Department of Justice (*id.* ¶ 161) is equally insufficient. A settlement is not factual matter supporting a reasonable inference of liability, Evid. Code § 1152(a) (“inadmissible to prove . . . liability”), and the allegation should be stricken from the Complaint, Civ. Proc. Code § 436(a); *e.g.*, *Lipsky v. Commonwealth United Corp.*, 551 F.2d 887, 893 (2d Cir. 1976) (holding that consent judgment with the SEC must be struck from the complaint because it was “not the result of an actual adjudication of any of the issues” and would be inadmissible at trial). Even if admitted, the DOJ’s contention was that twelve Questcor sales representatives went too far when providing meals and entertainment to certain doctors between 2009 and 2013. RJN Ex. H at 73. The settlement would not support HCSC’s claim for damages between 2014 and the present, and it should be stricken from the complaint as irrelevant matter, *Caliber Bodyworks*, 134 Cal. App. 4th at 385.

Finally, HCSC’s reliance on a 2018 study finding a correlation between prescriptions and payments (Cmplt. ¶ 158) overlooks that Mallinckrodt would have good reasons to select Acthar prescribers to speak about its uses. Thus, the study’s authors admit that their findings do not support a causal connection: “[T]he temporal sequence between payments and prescriptions cannot be definitely established. It is conceivable that the company preferentially sought out and supported

1 prominent prescribers of corticotrophin.” RJN Ex. I at 84. The study, then, does not make
2 “plausible,” *Prakashpalan*, 223 Cal. App. 4th at 1120, HCSC’s use of the label “bribe.”

3 (2) HCSC’s conclusory allegations that the payments and certifications of “compliance
4 with law” caused it injury are also entirely insufficient. Causation is a necessary element of each
5 of HCSC’s relevant causes of action.⁹ Thus, HCSC’s “pleading must show a cause and effect
6 relationship between the fraud and damages sought; otherwise no cause of action is stated.”
7 *Commonwealth Mortg. Assurance Co. v. Superior Court*, 211 Cal. App. 3d 508, 518 (1989).

8 However, as HCSC itself admits, Mallinckrodt’s payments to doctors since 2013 have been
9 *publicly disclosed* (*id.* ¶ 158), and HCSC pre-reviewed for medical necessity every claim for
10 coverage of an Acthar prescription (*id.* ¶ 271). HCSC of course knows which doctors prescribed
11 Acthar to its members and thus cannot plausibly allege to have relied on generic certifications of
12 compliance with law when covering Acthar prescriptions. *Bldg. Permit Consultants, Inc. v. Mazur*,
13 122 Cal. App. 4th 1400, 1415 (2004) (holding that plaintiff was incapable of alleging damages
14 where even in the absence of the defendant’s fraud the plaintiff would have suffered the same
15 injury); *Commonwealth Mortg. Assurance Co.*, 211 Cal. App. 3d at 518–21 (1989) (holding that
16 plaintiff failed to state a claim for fraud because it “fail[ed] to allege any causal connection between
17 the alleged representations . . . and [the plaintiff]’s decision to pay the claims submitted to it”).

18 Moreover, HCSC does not allege that the doctors were writing medically unnecessary or
19 otherwise inappropriate prescriptions. Thus, the doctors’ exercise of independent medical judgment
20 to prescribe Acthar, along with HCSC’s review of that judgment, are intervening factors breaking
21 the chain of causation as a matter of law. *Health Care Serv. Corp. v. Olivares*, No. 2:10-cv-221,
22 2011 WL 4591913, at *1, 6-7 (E.D. Tex. Sept. 2, 2011), *report and recommendation adopted*, No.
23 2:10-cv-221, 2011 WL 4591915 (E.D. Tex. Sept. 30, 2011) (dismissing claims against
24 pharmaceutical manufacturer for alleged off-label promotion and bribes to doctors where plaintiff
25

26 ⁹ Bob Cohen, *Right to Private Action Under State Consumer Protection Act—Preconditions*
27 *to Action*, 117 A.L.R.5th 155 § 2[a] (2004) (noting that “[a]ll reported decisions” on unfair and
28 deceptive practices acts “require a causal connection between the statutory violation and the
plaintiff’s loss or injury”); 10 *American Law of Torts* § 32:19 (2020) (“As in the case of torts in
general, causation is a link in the chain of fraud and deceit.”).

1 did not allege that the supposedly bribed physicians “relied on any Pfizer misrepresentation
 2 promoting an off-label use, as opposed to relying on the professional’s own judgment and expertise,
 3 when prescribing the drugs”); *Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d
 4 508, 529 (D.N.J. 2011) (rejecting payor’s claims when the payor failed to allege “any instances
 5 where Defendants provided remuneration to a physician and thereby caused the physician to
 6 prescribe [the relevant drug] when it was not in the patient’s best interests”).

7 **D. HCSC’s Allegations of Off-Label Promotion Lack the Particularity Necessary**
 8 **to Plead Fraud or Causation.**

9 HCSC advances sweeping, general allegations that Questcor engaged in off-label promotion
 10 of Acthar to “prop up” demand (Cmplt. ¶¶ 121-48) in an effort to support its claims under 34 states’
 11 unfair and deceptive trade practices acts (Count V) (*id.* ¶ 259) and the doctrine of common-law
 12 fraud (Count VI) (*id.* ¶¶ 272-73).¹⁰ But HCSC deliberately avoids alleging that the off-label
 13 statements it describes are false, and truthful statements about Acthar are protected speech even if
 14 beyond the label, *U.S. v. Caronia*, 703 F.3d 149, 165-69 (2012). These allegations fail to state a
 15 claim for two additional reasons.

16 (1) They lack the specificity required to satisfy the heightened pleading standard
 17 applicable to fraud. It is well-settled that, “[i]n California, fraud must be pled specifically; general
 18 and conclusory allegations do not suffice.” *Lazar v. Super. Ct.*, 12 Cal. 4th 631, 645 (1996); *see*
 19 *Gutierrez v. Carmax Auto Superstores California*, 19 Cal. App. 5th 1234, 1261 (2018) (requiring
 20 “reasonable particularity” for UCL claims). A complaint alleging fraud must “plead[] facts which
 21 show how, when, where, to whom, and by what means the representations were tendered,” *Lazar*,
 22 12 Cal. 4th at 645 (emphasis in original). HCSC’s generalized allegations regarding off-label

23
 24 ¹⁰ HCSC also includes, within its allegations, promotion for on-label uses that are entirely
 25 lawful. HCSC complains, for example, that Questcor “made an aggressive push” and “heavily
 26 marketed” Acthar for a variety of conditions for which Acthar “ha[d] been FDA approved.” (Cmplt.
 27 ¶¶ 147-48.) No liability can arise from such promotion. *E.g., Utts v. Bristol-Myers Squibb Co.*, 251
 28 F. Supp. 3d 644, 680 (S.D.N.Y. 2017) (rejecting fraud claim against a pharmaceutical company’s
 “dosing guidelines” for a drug, when the guidelines were “approved by the FDA as part of its review
 of [the drug’s] labeling”), *aff’d sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d
 Cir. 2019).

1 marketing fail to satisfy this “strict requirement of pleading,” *Stansfield v. Starkey*, 220 Cal. App.
2 3d 59, 73 (1990).

3 HCSC fails to “plead[] *facts* which show how, when, where, to whom, and by what means,”
4 *Lazar*, 12 Cal. 4th at 645, Questcor or Mallinckrodt allegedly marketed “off-label” use—such as
5 the so-called Brod protocol (Cmplt. ¶¶ 134-46). Although the Complaint is replete with vague
6 allegations that Acthar sales representatives were *educated* about the Brod protocol (Cmplt. ¶¶ 135-
7 136, 144), the Complaint contains only a single allegation that Questcor representatives actually
8 “*told* doctors, nurses, and other medical staff” they should implement the protocol (*id.* ¶ 145
9 (emphasis added)). Even that allegation is entirely conclusory, lacking any detail about who
10 allegedly made such statements, to whom and when. Simply put, HCSC fails to carry its burden of
11 alleging the particularities of any alleged fraud or that HCSC heard and relied on these statements
12 when covering Acthar prescriptions, thereby requiring dismissal. *See Wash. Cty.*, 2020 WL 43016,
13 at *11 (dismissing similar allegations that Questcor engaged in off-label promotion because
14 “Plaintiff does not allege that Plaintiff actually spoke to or received any false information from
15 KOLs or MSLs, rendering its conclusory assertions of reliance implausible”); *United States ex rel.*
16 *Worsfold v. Pfizer Inc.*, No. 09-11522-NMG, 2013 WL 6195790, at *5 (D. Mass. Nov. 22, 2013)
17 (finding “conclusory accusations” of marketing “‘plans and schemes’ [] insufficient” to satisfy
18 heightened pleading requirements).

19 (2) Any connection between Questcor’s promotion and any doctor’s decision to write a
20 prescription for Acthar is too attenuated for HCSC to meet its burden of pleading facts establishing
21 such a connection (*supra* at 20 & n. 9). Not only did HCSC pre-review each claim for an Acthar
22 prescription (*id.* ¶ 271), doctors exercised their own independent judgment as to whether certain
23 Acthar prescriptions were appropriate and medically necessary. Courts have held that the exercise
24 of that independent judgment breaks the chain of causation required to establish fraud-based claims.
25 *E.g., Sidney Hillman Health Center v. Abbott Labs.*, 873 F.3d 574, 577 (7th Cir. 2017) (holding that
26 where manufacturer promoted drug for ineffective purposes, a third-party payor’s suit failed for lack
27 of proximate cause, due to the need to “[d]isentagl[e] the effects of the improper promotions from
28 the many other influences on physicians’ prescribing practices”); *UFCW Local 1776 v. Eli Lilly &*

Co., 620 F.3d 121, 134 (2d Cir. 2010) (holding that the “attenuated link between the alleged misrepresentation made to doctors and ultimate injury to the [third-party payors]” defeated proximate cause).

E. HCSC’s Challenge to Questcor’s Acquisition of Synacthen Rights Fails to State a Claim.

To succeed on its claims that Questcor’s acquisition of the Synacthen “asset package” illegally maintained a monopoly (Count III) or otherwise unreasonably restrained trade (Count IV) under 32 states’ antitrust laws,¹¹ HCSC must allege and prove, among other things, that (a) the acquisition had a “substantially adverse effect on competition in the relevant market,” *Marsh*, 200 Cal. App. 4th at 495 (internal quotations omitted), and (b) as a result, HCSC suffered injury to its “business or property” from the reduction in competition. Bus. & Prof. Code § 16750(a); *Chicago Title Ins. Co. v. Great Western Fin. Corp.*, 69 Cal. 2d 305, 317–18 (1968) (quoting *Munter v. Eastman Kodak Co.*, 28 Cal. App. 660, 664–65 (1915)); RJN Ex. N (Table of Out of State Authorities IV).

“California requires a ‘high degree of particularity’ in the pleading of [antitrust] violations.” *Freeman v. San Diego Ass’n of Realtors*, 77 Cal. App. 4th 171, 196 (1999) (citing *Motors, Inc. v. Times Mirror Co.*, 102 Cal App. 3d 735, 742 (1980)). HCSC has failed to meet its pleading burden in two respects: (a) it fails to plead a relevant antitrust market in which Acthar competes, and (b) it has not plausibly alleged injury to its business or property. Moreover, having waited over seven years to challenge this asset acquisition, HCSC’s state law claims are barred by 32 applicable statutes of limitations.

¹¹ In selecting a California state court as the forum to bring these claims, HCSC overlooked the wrinkle that neither the Cartwright Act, unlike federal and most other state antitrust laws, nor the Unfair Competition Law contains prohibitions against monopolization or applies to mergers or asset acquisitions. *State of California ex rel. Van de Kamp v. Texaco, Inc.*, 46 Cal. 3d 1147, 1169 (1988) (interpreting Act to apply only to multi-firm trusts and combinations); *Freeman v. San Diego Ass’n of Realtors*, 77 Cal. App. 4th 171, 199-203 (1999); *but see Stop Youth Addiction v. Lucky Stores*, 17 Cal. 4th 553, 570 (1998) (questioning in *dictum* whether *Texaco* still applies to the UCL). Reference to those acts under Counts III and IV (Cmplt. ¶ 245(b) & 253(b)) should stricken for this reason alone. Mallinckrodt respectfully urges the Court to dismiss the remainder of these counts as well because, “in the interest of substantial justice,” that part of this action “should be heard in a forum outside this state,” Civ. Pro. Code § 410.30.

1 **1. HCSC Fails to Allege a Relevant Antitrust Market in which Acthar**
 2 **Competes.**

3 A proposed relevant antitrust market must be defined to include not only the defendant's
 4 specific product at issue (here Acthar), but also all "economic substitutes" for that product (*i.e.*,
 5 those that have a "reasonable interchangeability of use" or sufficient "cross-elasticity of demand"
 6 with the relevant product). *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962); *see*
 7 *also Redwood Theatres, Inc. v. Festival Enters., Inc.*, 200 Cal. App. 3d 687, 705 (1988) ("In antitrust
 8 law, the interchangeability of products is usually considered in the definition of markets."). In this
 9 way, the relevant antitrust market "includes actual or potential competitors who may take business
 10 away from each other." *Lloyd Design Corp. v. Mercedes Benz of N. Am., Inc.*, 66 Cal. App. 4th
 11 716, 724-25 (1998) (internal quotations omitted). A properly pled and proven antitrust market is an
 12 essential tool to be able to assess whether the challenged conduct constitutes a substantial harm to
 13 competition. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2285 (2018) (internal quotation marks
 14 omitted); *see also In re Cipro Cases I & II*, 348 P.3d 845, 869 (2015).

15 HCSC alleges a product market consisting of only "ACTH drugs" (Cmpl. ¶ 198) and that
 16 "Acthar represents 100% of the market" (*id.* ¶ 183). Pleading a single-product market is a common
 17 ploy by plaintiffs to overstate the effect on competition of the challenged conduct, and state and
 18 federal courts alike dismiss antitrust claims when it is clear that the proposed market excludes
 19 interchangeable products. *Hicks v. PGA Tour, Inc.*, 897 F.3d 1109, 1120–23 (9th Cir. 2018)
 20 (affirming dismissal of antitrust claims where plaintiffs' proposed product market "fail[ed] to
 21 include many reasonably interchangeable products" and was "contorted to meet their litigation
 22 needs") (internal quotations omitted); *Lloyd Design Corp.*, 66 Cal. App. 4th at 721 (affirming
 23 summary judgment where plaintiff "attempt[ed] to avoid defeat by pleading that the relevant product
 24 market is 'custom floor mats sold to Mercedes dealers for new cars'" because "neither product is
 25 unique but rather is one choice among many"); *Exxon Corp. v. Super. Ct.*, 51 Cal. App. 4th 1672,
 26 1682 (1997) (rejecting plaintiff's purported single-brand gasoline market as a matter of law where
 27 "the reasonable interchangeability for the purpose for which gasoline is produced (use in consumers'
 28 motor vehicles) mandates the relevant market to be all gasoline . . .").

HCSC has failed to meet its burden on this element because it proposes a market that, by HCSC's own admission, excludes non-ACTH products that are interchangeable with Acthar for particular conditions that Acthar is used to treat. HCSC admits that a variety of cheaper, non-ACTH alternatives exist for the treatment of certain of Acthar's approved indications. *See, e.g.*, Cmplt. ¶ 6 ("[O]ther than for a handful of similarly rare conditions, Acthar is either a drug of last resort or not known to be clinically effective."); ¶ 58 (recognizing "ibuprofen and certain over-the-counter NSAIDs in pill form" can be used in lieu of Acthar "to combat inflammation"); ¶ 66 ("For most indications, there is also a lack of evidence to support Acthar's use over lower-cost synthetic corticosteroids."); ¶ 68 (recognizing that, except for certain indications, Acthar was "not known to be more effective than simpler, cheaper, and more widely available drugs"); ¶ 89 (recognizing that for MS "Acthar had many cheaper, more effective competitors in that market"); ¶ 186 (recognizing Sabril as an alternative FDA-approved drug for the treatment of infantile spasms).

This admission by HCSC mandates dismissal of its antitrust claims.¹² Indeed, the court in *Humana* recently dismissed the federal and state antitrust claims by another TPP based on the same purported ACTH-only market, citing similar contradictory allegations in Humana's complaint and finding that Humana failed to include in its market definition all non-ACTH drugs reasonably interchangeable with Acthar. *Humana* Order at 7. Likewise here, HCSC's proposed "ACTH drug" market inappropriately excludes admitted economic substitutes for Acthar and thus would distort any analysis of the effect the Synacthen acquisition had on competition or Mallinckrodt's market power.

2. HCSC Fails to Allege Injury to its Business or Property from any Reduction in Competition as a Result of the Synacthen Acquisition.

HCSC's theory of causation and injury is, as it must be,¹³ that "but for" Questcor's acquisition, another firm would have purchased Synacthen and made it available in the United

¹² *See Bayer Schering Pharma AG v. Sandoz, Inc.*, 813 F. Supp. 2d 569, 577 (S.D.N.Y. 2011) (dismissing antitrust claims against drug manufacturer because the plaintiff "[did] not plead facts demonstrating that there [were] no other . . . drugs available to treat . . . [premenstrual dysphoric disorder]").

¹³ *See e.g., Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862 (D.C. Cir. 2008) ("A would-be purchaser suing an incumbent monopolist for excluding a potential competitor from which it might have bought a product at a lower price must prove the excluded firm was willing and able to supply

1 States, which would have forced the price of Acthar to fall. (Cmplt. ¶¶ 202-03.) HCSC also pleads
 2 that its damages period begins in 2011 (*id.* ¶ 200), more than two years *before* the allegedly unlawful
 3 acquisition, and alleges that “competition to Acthar would have begun prior to 2014 and would have
 4 included Synacthen” (*id.* ¶ 203).

5 HCSC, however, fails to offer “specific facts” making this connection between the allegedly
 6 anticompetitive conduct and injury plausible, which warrants dismissal of the claims, *see*
 7 *Prakashpalan v. Engstrom, Lipscomb & Lack*, 223 Cal. App. 4th 1105, 1120 (2014) (sustaining
 8 demurrer for failure to plead causation). Synacthen is not FDA approved for sale in the United
 9 States. “A plaintiff cannot be injured in fact by private conduct excluding [a competitive product]
 10 from the market when a statute prevents the [product] from entering that market in any event.”
 11 *Areeda & Hovenkamp, Antitrust Law*, ¶ 338b (4th ed. 2020). Thus, to plead a connection between
 12 the alleged conduct and its injury, HCSC must plead facts showing whether and when Synacthen
 13 would have gone through the extensive clinical trials to establish its safety and efficacy necessary
 14 to gain FDA approval an enter the market, 21 U.S.C. §§ 355(b) & (d). FDA approval would need
 15 to include specific indications that Acthar is also approved for in order for the drug to be marketed
 16 as a competitor to Acthar, and to cause injury, the approval would have to be for indications where
 17 Acthar has market power. The entrant would also have to win acceptance among doctors and payors
 18 as an effective and reliable alternative therapy. Only then would that product exert price pressure
 19 on Acthar.

20 Against this backdrop, HCSC’s failure to allege specific facts making plausible that FDA
 21 would approve Synacthen, which indications FDA would approve it for, and on what timetable
 22 those approvals would have occurred warrants dismissal of HCSC’s antitrust claims. *Compare*
 23 *Andrx Pharm., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 807–08, 815 (D.C. Cir. 2001) (upholding
 24 dismissal of an antitrust claim because plaintiff failed to allege facts demonstrating that FDA
 25 approval was probable) *and Brotech Corp. v. White Eagle Int’l Techs. Grp.*, No. 03-232, 2004 WL
 26 1427136, at *6 (E.D. Pa. June 21, 2004) (dismissing complaint where plaintiff failed to allege facts

27 _____
 28 it but for the incumbent firm’s exclusionary conduct.”); *Sunbeam Television Corp. v. Nielsen Media Research, Inc.*, 711 F.3d 1264, 1273 (11th Cir. 2013) (same).

1 showing timeframe for required FDA approval for product), *with Takeda Pharm. Co. Ltd. v. Zydus*
 2 *Pharm. (USA) Inc.*, 358 F. Supp. 3d 389, 398 (D.N.J. 2018) (holding that plaintiff had alleged
 3 antitrust injury by alleging that “the FDA indicated to Zydus that it was prepared to approve Zydus’
 4 [Abbreviated New Drug Application]”); *see also Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 862
 5 (D.C. Cir. 2008) (citation omitted) (holding that drug purchaser did not show it suffered antitrust
 6 injury because it failed to show that “but for [the] alleged misuse of [a] patent, the FDA would have
 7 granted [a competitor] final approval” by a particular date).

8 At a minimum, HCSC’s request for relief in the form of overcharge damages on each
 9 purchase of Acthar starting in 2011 or sometime prior to 2014 should be stricken from the
 10 Complaint. As HCSC admits, Mallinckrodt sublicensed rights to develop Synacthen in July 2017
 11 to a third party approved by the FTC.¹⁴ (Cmplt ¶ 176.) Yet HCSC has not alleged that Synacthen
 12 *even now* has FDA approval for sale in the United States, and it has not pleaded any facts about the
 13 sublicensee’s progress or anticipated timeframe to secure FDA approval. The real world has
 14 conclusively rebutted HCSC’s but-for world of competition from Synacthen prior to 2014. As
 15 such, the allegation is easily rejected at the pleading stage. *See Clark v. Leshner*, 106 Cal. App. 2d
 16 403, 408 (1951) (sustaining demurrer because “it is clear that the damage alleged occurred before
 17 the respondents had in the pursuit of their conspiracy arrived at a point where . . . they would be
 18 able to create and maintain restrictions [on competition in the market]”).

19 **3. HCSC’s Claims Are Barred by the Applicable Statutes of Limitations.**

20 Having waited seven years to challenge Questcor’s acquisition of rights to Synacthen,
 21 HCSC’s state-law antitrust claims are time-barred. The limitation period for the Cartwright Act and
 22 all but four of the other relevant states’ antitrust laws is four years, and the longest is six years. Bus.
 23 & Prof. Code § 16750(a) (establishing four-year period for claims under the Cartwright Act); RJN
 24 Ex. O (Table of Out of State Authorities V). A cause of action for an allegedly anticompetitive
 25 acquisition of assets accrues on the date of the acquisition. *Midwestern Mach. Co., Inc. v. Northwest*

26
 27 ¹⁴ HCSC’s reference to Mallinckrodt’s settlement with the FTC over Synacthen (Cmplt. ¶ 175)
 28 is inadmissible and should be stricken from the Complaint. (*Supra* at 19). In addition, the element
 of causation imposes a lower burden in a government enforcement than in private damages cases.
See United States v. Microsoft Corp., 253 F.3d 34, 79 (D.C. Cir. 2001).

Airlines, Inc., 392 F.3d 265, 271 (8th Cir. 2004) (holding that, under federal antitrust law, an “action challenging the initial acquisition of another company's stocks or assets accrues at the time of the merger or acquisition”); *Aryeh v. Canon Bus. Sols., Inc.*, 55 Cal. 4th 1185, 1195 (2013) (holding that federal antitrust law is instructive of law under the Cartwright Act). Therefore, the limitation periods on the claims asserted under California and all but four of the other relevant states’ antitrust laws expired no later than June 11, 2017, more than two and a half years before HCSC filed suit.

HCSC’s attempt to invoke tolling doctrines does not save its claims. HCSC’s references to “continuing” misconduct and harm (Cmplt. ¶ 181) are unavailing because once an acquisition is completed “no overt acts can be undertaken to further that plan.” *Midwestern Mach.*, 392 F.3d at 271 (“Otherwise, every business decision could qualify as a continuing violation to restart the statute of limitations as long as the firm continued to desire to be merged.”); *Z Techs. Corp. v. Lubrizol Corp.*, 753 F.3d 594, 599 (6th Cir. 2014) (rejecting continuing violations doctrine in Sherman Act § 2 challenge to an acquisition and subsequent price increases). HCSC’s allegations of “fraudulent concealment” fare no better because the acquisition was public (Cmplt. ¶¶ 165, 169–70). *See Midwestern Mach.*, 392 F.3d at 272 (reasoning that transactions “occur in the public eye and at a reasonably certain date”). Similarly, HCSC’s allegation that Mallinckrodt “falsely maintained that it would develop and seek FDA approval of Synacthen” (Cmplt. ¶ 177) is no basis to toll the limitation period because whether it secured FDA approval for Synacthen or not, Questcor’s acquisition of the right to decide not to price Synacthen in competition with Acthar would be the basis for any theory of harm to competition.

V. CONCLUSION

For the foregoing reasons, Mallinckrodt respectfully requests that the Court sustain its demurrer to the Complaint and each of its causes of action, or in the alternative, that the Court grant Mallinckrodt’s motion to strike various substantively defective allegations from the Complaint.

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1 Dated: May 20, 2020

Respectfully Submitted,

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3
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EXHIBIT 29

CM-015

ATTORNEY OR PARTY WITHOUT ATTORNEY (Name, State Bar number, and address): D. Eric Shapland (SBN 193853) ARNOLD & PORTER KAYE SCHOLER LLP 777 South Figueroa Street, 44th Floor Los Angeles, CA 90017-5844 TELEPHONE NO.: (213) 243-4000 x4238 FAX NO. (Optional): (213) 243-4199 E-MAIL ADDRESS (Optional): eric.shapland@arnoldporter.com ATTORNEY FOR (Name): Defendants	FOR COURT USE ONLY ENDORSED FILED ALAMEDA COUNTY MAY 28 2020 CLERK OF THE SUPERIOR COURT By <u>Jessica Flores</u> Deputy
SUPERIOR COURT OF CALIFORNIA, COUNTY OF ALAMEDA STREET ADDRESS: 1221 Oak Street MAILING ADDRESS: 1221 Oak Street CITY AND ZIP CODE: Oakland, CA 94612 BRANCH NAME: Oakland - Admin. Building	
PLAINTIFF/PETITIONER: Health Care Service Corp. DEFENDANT/RESPONDENT: Mallinckrodt ARC LLC, et al.	CASE NUMBER: RG20056354 JUDICIAL OFFICER: Hon. Judge Stephen Kaus
NOTICE OF RELATED CASE	DEPT.: 19

Identify, in chronological order according to date of filing, all cases related to the case referenced above.

1. a. Title: Humana Inc. v. Mallinckrodt ARD LLC, etc.
 - b. Case number: 2:19-cv-06926-DSF-MRW
 - c. Court: ☐ same as above
☒ other state or federal court (name and address): U.S. District Court, Central Dist. of California
 - d. Department: 7D
 - e. Case type: ☐ limited civil ☐ unlimited civil ☐ probate ☐ family law ☐ other (specify):
 - f. Filing date: August 8, 2019
 - g. Has this case been designated or determined as "complex?" ☐ Yes ☐ No
 - h. Relationship of this case to the case referenced above (check all that apply):
 - ☐ involves the same parties and is based on the same or similar claims.
 - ☒ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
 - ☐ involves claims against, title to, possession of, or damages to the same property.
 - ☐ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
 - ☐ Additional explanation is attached in attachment 1h
 - i. Status of case:
 - ☒ pending
 - ☐ dismissed ☐ with ☐ without prejudice
 - ☐ disposed of by judgment
2. a. Title:
 - b. Case number:
 - c. Court: ☐ same as above
☐ other state or federal court (name and address):
 - d. Department:

CM-015

PLAINTIFF/PETITIONER: Health Care Service Corp.	CASE NUMBER: RG20056354
DEFENDANT/RESPONDENT: Mallinckrodt ARC LLC, et al.	

2. (continued)

- e. Case type: ☐ limited civil ☐ unlimited civil ☐ probate ☐ family law ☐ other (specify):
- f. Filing date:
- g. Has this case been designated or determined as "complex?" ☐ Yes ☐ No
- h. Relationship of this case to the case referenced above (check all that apply):
- ☐ involves the same parties and is based on the same or similar claims.
- ☐ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- ☐ involves claims against, title to, possession of, or damages to the same property.
- ☐ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
- ☐ Additional explanation is attached in attachment 2h
- i. Status of case:
- ☐ pending
- ☐ dismissed ☐ with ☐ without prejudice
- ☐ disposed of by judgment

3. a. Title:

b. Case number:

- c. Court: ☐ same as above
☐ other state or federal court (name and address):

d. Department:

e. Case type: ☐ limited civil ☐ unlimited civil ☐ probate ☐ family law ☐ other (specify):

f. Filing date:

g. Has this case been designated or determined as "complex?" ☐ Yes ☐ No

h. Relationship of this case to the case referenced above (check all that apply):

- ☐ involves the same parties and is based on the same or similar claims.
- ☐ arises from the same or substantially identical transactions, incidents, or events requiring the determination of the same or substantially identical questions of law or fact.
- ☐ involves claims against, title to, possession of, or damages to the same property.
- ☐ is likely for other reasons to require substantial duplication of judicial resources if heard by different judges.
- ☐ Additional explanation is attached in attachment 3h

i. Status of case:

- ☐ pending
- ☐ dismissed ☐ with ☐ without prejudice
- ☐ disposed of by judgment

4. ☐ Additional related cases are described in Attachment 4. Number of pages attached: _____

Date: May 20, 2020

D. Eric Shapland

(TYPE OR PRINT NAME OF PARTY OR ATTORNEY)

(SIGNATURE OF PARTY OR ATTORNEY)

PLAINTIFF/PETITIONER: Health Care Service Corp.	CASE NUMBER: RG20056354
DEFENDANT/RESPONDENT: Mallinckrodt ARC LLC, et al.	

**PROOF OF SERVICE BY FIRST-CLASS MAIL
NOTICE OF RELATED CASE**

(NOTE: You cannot serve the Notice of Related Case if you are a party in the action. The person who served the notice must complete this proof of service. The notice must be served on all known parties in each related action or proceeding.)

1. I am at least 18 years old and **not a party to this action**. I am a resident of or employed in the county where the mailing took place, and my residence or business address is (*specify*):

2. I served a copy of the *Notice of Related Case* by enclosing it in a sealed envelope with first-class postage fully prepaid and (*check one*):
 - a. ☐ deposited the sealed envelope with the United States Postal Service.
 - b. ☐ placed the sealed envelope for collection and processing for mailing, following this business's usual practices, with which I am readily familiar. On the same day correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service.

3. The *Notice of Related Case* was mailed:
 - a. on (*date*):
 - b. from (*city and state*):

4. The envelope was addressed and mailed as follows:

a. Name of person served:

Street address:

City:

State and zip code:

c. Name of person served:

Street address:

City:

State and zip code:

b. Name of person served:

Street address:

City:

State and zip code:

d. Name of person served:

Street address:

City:

State and zip code:

☐ Names and addresses of additional persons served are attached. (*You may use form POS-030(P).*)

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Date:

(TYPE OR PRINT NAME OF DECLARANT)

(SIGNATURE OF DECLARANT)

PROOF OF SERVICE

1. I am over eighteen years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 777 South Figueroa Street, Forty-Fourth Floor, Los Angeles, California 90017-5844.
2. On **May 20, 2020**, I served the following document(s) with a hearing date and judicial assignment that were subsequently vacated, and on **May 28, 2020**, I served the same following documents with an updated hearing date and judicial assignment:

NOTICE OF RELATED CASE

3. I served the document(s) on the following person(s):

[SEE ATTACHED SERVICE LIST]

4. The documents were served by the following means:

- ☐ **By U.S. Mail.** I enclosed the document(s) in a sealed envelope or package addressed to the person(s) at the address(es) in Item 3 and (**check one**):
- ☐ deposited the sealed envelope with the United States Postal Service, with the postage fully prepaid.
- ☐ placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for mailing. On the same day the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.
- I am employed in the county where the mailing occurred. The envelope or package was placed in the mail at Los Angeles, California.
- ☐ **By Overnight Delivery/Express Mail.** I enclosed the documents and an unsigned copy of this declaration in a sealed envelope or package designated by **[name of delivery company or U.S. Postal Service for Express Mail]** addressed to the persons at the address(es) listed in Item 3, with **[Express Mail postage or, if not Express Mail, delivery fees]** prepaid or provided for. I placed the sealed envelope or package for collection and delivery, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for express delivery. On the same day the correspondence is collected for delivery, it is placed for collection in the ordinary course of business in a box regularly maintained by **[name of delivery company or U.S. Postal Service for Express Mail]** or delivered to a courier or driver authorized by **[name of delivery company]** to receive documents.
- ☐ **By Messenger Service.** I served the documents by placing them in an envelope or package addressed to the persons at the address(es) listed in Item 3 and providing them to a professional messenger service for service. (See attached Declaration(s) of Messenger.)

- 1 ☐ **By Facsimile Transmission.** Based on an agreement between the parties to accept service
 2 by facsimile transmission, which was confirmed in writing, I faxed the document(s) and an
 3 unsigned copy of this declaration to the person(s) at the facsimile numbers listed in Item 3
 4 on **May 28, 2020**, at **[type time]**. The transmission was reported as complete without error
 by a transmission report issued by the facsimile machine that I used immediately following
 the transmission. A true and correct copy of the facsimile transmission report, which I
 printed out, is attached hereto.
- 5 ☒ **By Electronic Service (E-mail).** Based on California Rule of Court 2.251(c)(3), or on a
 6 court order, or on an agreement of the parties to accept service by electronic transmission, I
 7 transmitted the document(s) to the person(s) at the electronic notification address(es) listed
 8 in Item 3 on **May 20, 2020 and May 28, 2020**.
- 9 ☐ **Via Court Notice of Electronic Filing.** The document(s) will be served by the court via
 10 NEF and hyperlink to the document(s). On **May 28, 2020**, I checked the CM/ECF docket
 11 for this case or adversary proceeding and determined that the person(s) listed in Item 3 are
 12 on the Electronic Mail Notice List to receive NEF transmission at the email addresses
 13 indicated in Item 3 **[or on the attached service list, if applicable]**.
- 14 ☐ **Via Electronic Notification.** The document(s) will be served via electronic notification on
 15 **May 28, 2020** on the person(s) listed in Item 3 at the email addresses indicated in Item 3
 16 **[or on the attached service list, if applicable]**.
- 17 ☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the
 18 foregoing is true and correct.
- 19 ☐ **FEDERAL:** I declare that I am employed in the office of a member of the bar of this court
 20 at whose direction the service was made.

21 Dated: **May 28, 2020.**

22 Signature: _____

23 Type or Print Name: Kathryn Jensen

24 E-Service Address: kathryn.jensen@arnoldporter.com

Health Care Service Corp. v. Mallinckrodt ARD LLC, etc., et al.
Alameda Superior Court Case No. RG20056354

SERVICE LIST

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Jason H. Kim
Matthew S. Weiler
Kyle G. Bates
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2000 Powell Street, Suite 1400
Emeryville, CA 94608
Telephone: (415) 421-7100
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*Counsel for Plaintiff
Health Care Service
Corporation*

Peter D. St. Phillip
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Renee A. Nolan
One Tower Bridge
100 Front Street, Suite 520
West Conshohocken, PA 19428
Telephone: (215) 399-4770
rnolan@lowey.com

EXHIBIT 30

ENDORSED
FILED
ALAMEDA COUNTY

MAY 28 2020

CLERK OF THE SUPERIOR COURT

By

[Signature]
Deputy

ARNOLD & PORTER KAYE SCHOLER LLP

Matthew M. Wolf (*PHV* to be filed)

Laura S. Shores (*PHV* to be filed)

Sonia Kuester Pfaffenroth (SBN 223984)

Michael B. Bernstein (*PHV* to be filed)

Adam M. Pergament (SBN 267557)

601 Massachusetts Avenue, N.W.

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Telephone: (213) 243-4000

Facsimile: (213) 243-4199

eric.shapland@arnoldporter.com

Attorneys for Defendants

Mallinckrodt ARD LLC and Mallinckrodt plc

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

PROOF OF SERVICE

Date: August 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Res. Nos. 2179414 & 2179416

Action Filed: February 27, 2020

PROOF OF SERVICE

Ex. 30
p. 350

PROOF OF SERVICE

1. I am over eighteen years of age and not a party to this action. I am employed in the County of Los Angeles, State of California. My business address is 777 South Figueroa Street, Forty-Fourth Floor, Los Angeles, California 90017-5844.
2. On May 20, 2020, I served the following document(s) with a hearing date and judicial assignment that were subsequently vacated, and on May 28, 2020, I served the same following documents with an updated hearing date and judicial assignment:

THE DEFENDANT MALLINCKRODT ENTITIES' NOTICE OF DEMURRER AND DEMURRER TO HCSC'S COMPLAINT; SHAPLAND DECLARATION

DEFENDANT MALLINCKRODT ENTITIES' NOTICE OF MOTION AND MOTION TO STRIKE ALLEGATIONS FROM PLAINTIFF HCSC'S COMPLAINT; SHAPLAND DECLARATION

THE DEFENDANT MALLINCKRODT ENTITIES' MEMORANDUM IN SUPPORT OF DEMURRER AND MOTION TO STRIKE

REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF THE DEFENDANT MALLINCKRODT ENTITIES' DEMURRER AND MOTION TO STRIKE

[PROPOSED] ORDER SUSTAINING THE DEFENDANT MALLINCKRODT ENTITIES' DEMURRER TO HCSC'S COMPLAINT

[PROPOSED] ORDER GRANTING DEFENDANT MALLINCKRODT ENTITIES' MOTION TO STRIKE ALLEGATIONS FROM PLAINTIFF HCSC'S COMPLAINT

3. I served the document(s) on the following person(s):

[SEE ATTACHED SERVICE LIST]

4. The documents were served by the following means:

☐ **By U.S. Mail.** I enclosed the document(s) in a sealed envelope or package addressed to the person(s) at the address(es) in Item 3 and **(check one)**:

☐ deposited the sealed envelope with the United States Postal Service, with the postage fully prepaid.

☐ placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for mailing. On the same day the correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

I am employed in the county where the mailing occurred. The envelope or package was placed in the mail at Los Angeles, California.

- ☐ **By Overnight Delivery/Express Mail.** I enclosed the documents and an unsigned copy of this declaration in a sealed envelope or package designated by [name of delivery company or U.S. Postal Service for Express Mail] addressed to the persons at the address(es) listed in Item 3, with [Express Mail postage or, if not Express Mail, delivery fees] prepaid or provided for. I placed the sealed envelope or package for collection and delivery, following our ordinary business practices. I am readily familiar with this business' practice for collecting and processing correspondence for express delivery. On the same day the correspondence is collected for delivery, it is placed for collection in the ordinary course of business in a box regularly maintained by [name of delivery company or U.S. Postal Service for Express Mail] or delivered to a courier or driver authorized by [name of delivery company] to receive documents.
- ☐ **By Messenger Service.** I served the documents by placing them in an envelope or package addressed to the persons at the address(es) listed in Item 3 and providing them to a professional messenger service for service. (See attached Declaration(s) of Messenger.)
- ☐ **By Facsimile Transmission.** Based on an agreement between the parties to accept service by facsimile transmission, which was confirmed in writing, I faxed the document(s) and an unsigned copy of this declaration to the person(s) at the facsimile numbers listed in Item 3 on **May 28, 2020**, at [type time]. The transmission was reported as complete without error by a transmission report issued by the facsimile machine that I used immediately following the transmission. A true and correct copy of the facsimile transmission report, which I printed out, is attached hereto.
- ☒ **By Electronic Service (E-mail).** Based on California Rule of Court 2.251(c)(3), or on a court order, or on an agreement of the parties to accept service by electronic transmission, I transmitted the document(s) to the person(s) at the electronic notification address(es) listed in Item 3 on **May 20, 2020 and May 28, 2020**.
- ☐ **Via Court Notice of Electronic Filing.** The document(s) will be served by the court via NEF and hyperlink to the document(s). On **May 28, 2020**, I checked the CM/ECF docket for this case or adversary proceeding and determined that the person(s) listed in Item 3 are on the Electronic Mail Notice List to receive NEF transmission at the email addresses indicated in Item 3 [or on the attached service list, if applicable].
- ☐ **Via Electronic Notification.** The document(s) will be served via electronic notification on **May 28, 2020** on the person(s) listed in Item 3 at the email addresses indicated in Item 3 [or on the attached service list, if applicable].
- ☒ **STATE:** I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.
- ☐ **FEDERAL:** I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made.

Dated: **May 28, 2020**.

Signature: Kathryn Jensen

Type or Print Name: Kathryn Jensen

E-Service Address:

kathryn.jensen@arnoldporter.com

Health Care Service Corp. v. Mallinckrodt ARD LLC, etc., et al.
Alameda Superior Court Case No. RG20056354

SERVICE LIST

Todd M. Schneider
Jason H. Kim
Matthew S. Weiler
Kyle G. Bates

*Counsel for Plaintiff
Health Care Service
Corporation*

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Renee A. Nolan
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West Conshohocken, PA 19428
Telephone: (215) 399-4770
rnolan@lowey.com



Superior Court of California, County of Alameda
 Rene C. Davidson Alameda County Courthouse
 1225 Fallon Street
 Oakland, CA 94612

Receipt Nbr: 922127
 Clerk: jflores
 Date: 05/29/2020

Type	Case Number	Description	Amount
Filing	RG20056354	Initial Appearance	\$435.00
Filing	RG20056354	Complex Fee - Adverse Party	\$1000.00
Filing	RG20056354	Initial Appearance	\$435.00
Filing	RG20056354	Complex Fee - Adverse Party	\$1000.00
Filing	RG20056354	Demurrer to Complaint	\$60.00

Total Amount Due: \$2,930.00
 Prior Payment:
 Current Payment: \$2,930.00
 Balance Due: \$.00
 Overage:
 Excess Fee:
 Change:

Payment Method:
 Cash:
 Check: \$2,930.00

EXHIBIT 31

1 ARNOLD & PORTER KAYE SCHOLER LLP

2 Matthew M. Wolf (*PHV* to be filed)

3 Laura S. Shores (*PHV* to be filed)

4 Sonia Kuester Pfaffenroth (SBN 223984)

5 Michael B. Bernstein (*PHV* to be filed)

6 Adam M. Pergament (SBN 267557)

7 601 Massachusetts Avenue, N.W.

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9 Telephone: (202) 942-5000

10 Facsimile: (202) 942-5999

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12 laura.shores@arnoldporter.com

13 sonia.pfaffenroth@arnoldporter.com

14 michael.b.bernstein@arnoldporter.com

15 adam.pergament@arnoldporter.com

16 D. Eric Shapland (SBN 193853)

17 777 South Figueroa Street, 44th Floor

18 Los Angeles, CA 90017-5844

19 Telephone: (213) 243-4000

20 Facsimile: (213) 243-4199

21 eric.shapland@arnoldporter.com

22 *Attorneys for Defendants*

23 *Mallinckrodt ARD LLC and Mallinckrodt plc*

24 SUPERIOR COURT OF THE STATE OF CALIFORNIA

25 COUNTY OF ALAMEDA

26 HEALTH CARE SERVICE CORP.,

27 Plaintiff,

28 v.

29 MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
30 ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
31 MALLINCKRODT plc,

32 Defendants.

Case No. RG20056354

**[PROPOSED] ORDER GRANTING
DEFENDANT MALLINCKRODT
ENTITIES' MOTION TO STRIKE
ALLEGATIONS FROM PLAINTIFF
HCSC'S COMPLAINT**

Date: Aug. 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Reservation No. R-2179416

Action Filed: February 27, 2020

The Court GRANTS Defendant Mallinckrodt ARD LLC and Mallinckrodt plc's Motion to Strike Allegations from Plaintiff HCSC's Complaint.

DATED: _____, 2020

[PROP.] ORDER GRANTING MOT. TO STRIKE ALLEGATIONS FROM COMPLT.

EXHIBIT 32

MAY 28 2020

1 ARNOLD & PORTER KAYE SCHOLER LLP

2 Matthew M. Wolf (*PHV* to be filed)

3 Laura S. Shores (*PHV* to be filed)

4 Sonia Kuester Pfaffenroth (SBN 223984)

5 Michael B. Bernstein (*PHV* to be filed)

6 Adam M. Pergament (SBN 267557)

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18 Los Angeles, CA 90017-5844

19 Telephone: (213) 243-4000

20 Facsimile: (213) 243-4199

21 eric.shapland@arnoldporter.com

22 *Attorneys for Defendants*

23 *Mallinckrodt ARD LLC and Mallinckrodt plc*

24 SUPERIOR COURT OF THE STATE OF CALIFORNIA

25 COUNTY OF ALAMEDA

26 HEALTH CARE SERVICE CORP.,

27 Plaintiff,

28 v.

29 MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
30 ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
31 MALLINCKRODT plc,

32 Defendants.

Case No. RG20056354

**[PROPOSED] ORDER SUSTAINING
THE DEFENDANT
MALLINCKRODT ENTITIES'
DEMURRER TO HCSC'S
COMPLAINT**

Date: Aug. 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Reservation No. R-2179414

Action Filed: February 27, 2020

BY FAX

[PROP.] ORDER SUSTAINING DEMURRER TO COMPLAINT

Ex. 32
p. 359

Ex. 32
p. 360

EXHIBIT 33

ARNOLD & PORTER KAYE SCHOLER LLP

Matthew M. Wolf (*PHV* to be filed)

Laura S. Shores (*PHV* to be filed)

Sonia Kuester Pfaffenroth (SBN 223984)

Michael B. Bernstein (*PHV* to be filed)

Adam M. Pergament (SBN 267557)

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Los Angeles, CA 90017-5844

Telephone: (213) 243-4000

Facsimile: (213) 243-4199

eric.shapland@arnoldporter.com

Attorneys for Defendants

Mallinckrodt ARD LLC and Mallinckrodt plc

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**REQUEST FOR JUDICIAL NOTICE
IN SUPPORT OF THE DEFENDANT
MALLINCKRODT ENTITIES'
DEMURRER AND MOTION TO
STRIKE**

Date: August 5, 2020

Time: 3:00 p.m.

Dept: 19

Judge: Hon. Stephen Kaus

Res. Nos. 2179414 & 2179416

Action Filed: February 27, 2020

ENDORSED
FILED
ALAMEDA COUNTY

MAY 28 2020

CLERK OF THE SUPERIOR COURT

By

Jessica Flannery Deputy

In support of its contemporaneously filed demurrer and motion to strike Plaintiff Health Care Services Corporation's Complaint, Defendants Mallinckrodt ARD LLC and Mallinckrodt plc respectfully request that the Court take judicial notice, pursuant to Cal. Evid. Code §§ 451-53, of the following documents:

Exhibit	Document	Page
A	Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees ("2005 SAB"), 70 Fed. Reg. 70,623 (Nov. 22, 2005).	7
B	Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs ("2014 SAB"), 79 Fed. Reg. 31,120 (May 30, 2014).	14
C	Bill Alpert, <i>Too Close for Comfort</i> , BARRON'S, Oct. 19, 2013, <i>which is publicly available at</i> https://www.barrons.com/articles/too-close-for-comfort-1382170462 .	19
D	Andrew Pollack, <i>Drug Maker's Donations to Co-Pay Charity Face Scrutiny</i> , N.Y. TIMES, Dec. 18, 2013, <i>which is publicly available at</i> https://www.nytimes.com/2013/12/19/business/shake-up-at-big-co-pay-fund-raises-scrutiny-on-similar-charities.html .	25
E	FDA Orphan Drug Designations and Approvals Search, H.P. Acthar Gel, <i>which is publicly available at</i> https://www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=168103 .	32
F	Letter from Dir. Russel Katz, M.D., Div. of Neurology Products, Center for Drug Evaluation and Research, Dep't of Health and Human Services, to Questcor Pharmaceuticals, NDA Approval Letter for NDA 022432 (Oct. 15, 2010), <i>which is published publicly by the FDA at</i> https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432_hp_acthar_gel_toc.cfm , <i>and this direct link</i> , https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s000Approv.pdf .	35
G	Center for Drug Evaluation and Research, Labeling for H.P. Acthar Gel (Oct. 15, 2010), <i>which is published publicly by the FDA at</i> https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432_hp_acthar_gel_toc.cfm , <i>and this direct link</i> , https://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022432Orig1s000LBL.pdf .	45

Exhibit	Document	Page
H	Press Release, Dep't of Justice, Drug Maker Mallinckrodt Agrees to Pay Over \$15 Million to Resolve Alleged False Claims Act Liability for "Wining and Dining" Doctors (Sept. 4, 2019), <i>which is published publicly by the Department of Justice at</i> https://www.justice.gov/opa/pr/drug-maker-mallinckrodt-agrees-pay-over-15-million-resolve-alleged-false-claims-act-liability .	72
I	Daniel M. Hartung, PharmD, MPH; Kirbee Johnston, MPH, David M. Cohen, MD, et al, Industry Payments to Physician Specialists Who Prescribe Repository Corticotropin (June 29, 2018), <i>which is publicly available at</i> https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2686039 .	75
J	<i>Humana Inc. v. Mallinckrodt ARD LLC</i> , No. CV 19-06926, split op. (C.D. Cal. Mar. 9, 2020) (Dkt. No. 57).	89
K	Table of Out of State Authorities I (Count VII—Relevant Insurance Fraud Statutes & Lack of Private Enforcement Mechanisms (or Legal Defenses in Lieu)).	125
L	Table of Out of State Authorities II (Counts III, IV & V—Relevant States' Authorities Adopting Standards for Analyzing Rule of Reason for Nonprice Vertical Restraints).	132
M	Table of Out of State Authorities III (Count V—Relevant State Unfair and Deceptive Trade Practices Acts & Limitations Periods (or Legal Defenses in Lieu)).	139
N	Table of Out of State Authorities IV (Count's III & IV—Relevant State Antitrust Acts Requirements re Injury).	144
O	Table of Out of State Authorities V (Counts III & IV—Relevant State Antitrust Acts & Limitations Periods).	152

SUPPORTING ARGUMENT

"When any ground for objection to a complaint . . . appears . . . from any matter of which the court is required to or may take judicial notice, the objection on that ground may be taken by a demurrer to the pleading." Civ. Proc. Code § 430.30(a). Certain records must be judicially noticed. Evid. Code § 451. Others may be judicially noticed. Id. § 452. In the latter case, notice becomes mandatory when (1) a party has given sufficient notice of its request "through the pleadings or otherwise, to enable [the] adverse party to prepare to meet the request" and (2) the party has "furnished the court with sufficient information to enable it to take judicial notice of the matter."

1 Cal. Evid. § 453; see *Licudine v. Cedars-Sinai Med. Ctr.*, 3 Cal. App. 5th 881, 902 (Ct. App. 2016)
 2 (“[T]he court’s discretion to take judicial notice of these matters disappears—and the court becomes
 3 obligated to judicially notice these matters—if the moving party gives adequate advance notice.”).

4 This court must take judicial notice of documents filed on the Federal Register, both for the
 5 fact of their publication and for their content. Evid. Code § 451(b) (“Judicial notice shall be taken
 6 of the following: any matter made a subject of judicial notice . . . by Section 1507 of Title 44 of the
 7 United States Code.”); 44 U.S.C. § 1507 (“The contents of the Federal Register shall be judicially
 8 noticed. . .”). The records indicated in Exhibits A and B are records to be noticed under this rule.

9 This court may take judicial notice of [o]fficial acts of the . . . executive . . . departments of
 10 the United States.” Evid. Code § 452(c). The records indicated in Exhibits E through H are such
 11 executive records noticeable under this rule. *Licudine v. Cedars-Sinai Med. Ctr.*, 3 Cal. App. 5th
 12 881, 902 (Ct. App. 2016) (“[W]e can take judicial notice of official acts and public records. . .)
 13 (quoting *In re Joseph H.*, 237 Cal. App. 4th 517, 541–42 (2015)).¹ Exhibits E, F and G are offered
 14 merely for official acts of the FDA in giving Acthar orphan drug status, approving its indication
 15 for infantile spasms, and approving all its current indications and labeling. Exhibit H is merely
 16 offered for the indisputable fact Department of Justice reports that its settlement with Mallinckrodt
 17 over payments to doctors were for allegations that were limited to the conduct of “twelve Questcor
 18 sales representatives” “from 2009 and 2013.” These acts are subject to mandatory judicial notice
 19 as (1) this filing serves as sufficient notice to the plaintiff in this action and (2) the true and accurate
 20 copies attached (and the internet addresses listed above) provide sufficient information to the Court
 21 to satisfy Evid. Code § 453.

22 The court may notice “[f]acts and propositions that are not reasonably subject to dispute and
 23 are capable of immediate and accurate determination by resort to sources of reasonably indisputable
 24 accuracy.” Evid. Code § 452(h). California courts take judicial notice of the existence and content
 25 of newspaper articles and other documents published online. See *Norgart v. Upjohn Co.*, 21 Cal.
 26 4th 383, 408, n.6 (1999) (taking judicial notice under Evid. Code § 452(h) of *when* controversy

27 ¹ The comments by the Assembly Committee on Judiciary to Evid. Code § 452(c) note:
 28 “Under this provision, the California courts have taken judicial notice of a wide variety of
 administrative and executive acts, such as proceedings and reports”

1 about a pharmaceutical product had “arisen in the popular press” in the context of a grant of
 2 summary judgment on statute of limitations grounds); *Hurvitz v. Hoefflin*, 84 Cal. App. 4th 1232,
 3 1235, 101 Cal. Rptr. 2d 558, 561 n.1 (2000) (taking judicial notice of “existence and contents of”
 4 various “press clippings”); *Ragland v. U.S. Bank Nat’l Assn.*, 209 Cal. App. 4th 182, 193 (2012)
 5 (“[W]e may take judicial notice of the existence of . . . [w]eb sites, and blogs.”). The records
 6 indicated in Exhibits C, D and I reflect such facts noticeable under this rule. As detailed in the
 7 demurrer, Defendants offer Exhibits C and D only for the indisputable facts that these articles were
 8 published by *Barron’s* and *The New York Times* on October 19, 2013 and December 18, 2013,
 9 respectively, and that the articles detail concerns of misconduct around single-drug co-payment
 10 assistance funds and donations to such funds by Questcor in particular. Equally, Defendants offer
 11 Exhibit I, originally cited by Plaintiffs at paragraph 158 of the Complaint, for the fact of the author’s
 12 statements; not the truth of the study’s conclusions or for any particular interpretations of the
 13 underlying facts. *See Fremont Indem. Co. v. Fremont Gen. Corp.*, 148 Cal. App. 4th 97, 113 (2007)
 14 (“Although the existence of a document may be judicially noticeable, the truth of statements
 15 contained in the document and its proper interpretation are not subject to judicial notice if those
 16 matters are reasonably disputable.”) (citing *StorMedia, Inc. v. Superior Court*, 20 Cal. 4th 449, 457,
 17 n.9 (1999)). Defendants respectfully suggest that the court must notice these laws as (1) this filing
 18 serves as sufficient notice to the plaintiffs and (2) the true and accurate copies attached (and the
 19 internet addresses listed above) provide sufficient information to the Court to satisfy Cal. Evid.
 20 Code § 453.

21 This Court may take judicial notice of “[r]ecords of (1) any court of this state or (2) any
 22 court of record of the United States or of any state of the United States.” Evid. Code § 452(d). The
 23 order provided at Exhibit J is a court record noticeable under this rule. Defendants offer this record
 24 only for the “ruling and the basis for that ruling”: that the *Humana* court issued an opinion on March
 25 9, 2020 that ruled against similar plaintiffs on nearly identical facts. Defendants do not offer these
 26 records for the court to accept “the truth of a prior court’s factual findings.” *See Hart v. Darwish*,
 27 12 Cal. App. 5th 218, 225 (Ct. App. 2017). These documents are subject to mandatory judicial
 28

1 notice as (1) this filing serves as sufficient notice to plaintiff and (2) the true and accurate copy
2 attached provides sufficient information to the Court to satisfy Evid. Code § 453.

3 Finally, “[t]he decisional, constitutional, and statutory law of any state of the United States”
4 may be judicially noticed by the Court. Evid. Code § 452.² The tables provided at Exhibits K
5 through O reflect compilations of just such laws. These laws are subject to mandatory judicial
6 notice as (1) this filing serves as sufficient notice to the plaintiff and (2) the citations in Exhibits J-
7 M provide sufficient information to the Court to satisfy Evid. Code § 453. In the alternative,
8 Defendants ask the court to take this request for judicial notice as a citation to published materials.
9 *Quelimane Co. v. Stewart Title Guar. Co.*, 19 Cal. 4th 26, 46 n. 9 (1998), as modified (Sept. 23,
10 1998).

11
12 Dated: May 20, 2020

Respectfully Submitted,

ARNOLD & PORTER KAY SCHOLER LLP

13
14
15 By: 

D. Eric Shapland

16
17 *Attorneys for Defendant*
18 *Mallinckrodt ARD LLC and*
19 *Mallinckrodt plc*
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27 ² Evid. Code § 220 defines “state” in this circumstance as “any state, district,
28 commonwealth, territory, or insular possession of the United States,” which includes the District
of Columbia and the territory of Puerto Rico.

EXHIBIT A

it to the agency. Thus, each firm submitting a compliance extension request will need 5 hours of employee time to complete the request. Given that 56 businesses are expected to submit written requests in year one, the total burden hours for year one are 280.

In year two, FDA expects about one-half as many firms to request a labeling compliance extension. So for year two, 28 firms are expected to file a request for an extension to the labeling compliance date. Again, assuming that it will take 5 hours to complete each request, the total burden hours for year two will be 140.

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23040 Filed 11–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0343]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Guidance for Requesting an Extension to Use Existing Label Stock after the Trans Fat Labeling Effective Date of January 1, 2006” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing an opportunity for public comment on this collection of information. Since this collection received emergency approval that expires on January 1, 2006, FDA is following the normal PRA clearance procedures by issuing that notice.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 2005 (70 FR 52108), the agency announced that the proposed information collection

had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0571. The approval expires on January 31, 2006. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: November 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–23041 Filed 11–21–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: December 12, 2005, 9 a.m.—5 p.m., EST.

Place: Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Monday, December 12, from 9 a.m. to 5 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–800–369–6048 on December 12 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the December meeting will include, but are not limited to: A summary of the U.S. Court of Federal Claims' 18th Judicial Conference; a report from the ACCV Workgroup looking at proposed guidelines for future changes to the Vaccine Injury Table; and updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics and Evaluation Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

Public Comments: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Ms. Cheryl Lee, Principal Staff Liaison, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services

Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or e-mail cleee@hrsa.gov. Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–2124 or e-mail cleee@hrsa.gov.

Dated: November 15, 2005.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 05–23042 Filed 11–21–05; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: OIG periodically develops and issues guidance, including Special Advisory Bulletins, to alert and inform the health care industry about potential problems or areas of special interest. This **Federal Register** notice sets forth the recently issued OIG Special Advisory Bulletin addressing patient assistance programs for Medicare Part D enrollees.

FOR FURTHER INFORMATION CONTACT: Darlene M. Hampton, Office of Counsel to the Inspector General, (202) 619–0335.

SUPPLEMENTARY INFORMATION:

Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees (November 2005)

I. Introduction

Patient assistance programs (PAPs) have long provided important safety net assistance to patients of limited means

who do not have insurance coverage for drugs, typically serving patients with chronic illnesses and high drug costs. PAPs are structured and operated in many different ways. PAPs may offer cash subsidies, free or reduced price drugs, or both. Some PAPs offer assistance directly to patients, while others replenish drugs furnished by pharmacies, clinics, hospitals, and other entities to eligible patients whose drugs are not covered by an insurance program. Some PAPs are affiliated with particular pharmaceutical manufacturers; others are operated by independent charitable organizations (such as, for example, patient advocacy and support organizations) without regard to any specific donor or industry interests.

Many pharmaceutical manufacturers have historically sponsored PAPs that assist patients whose outpatient prescription drugs are not covered by an insurance program (including some Medicare beneficiaries), in obtaining the manufacturer's products for free or at greatly reduced cost. Beginning on January 1, 2006, Medicare Part D will offer Medicare beneficiaries who elect to enroll broad coverage for outpatient prescription drugs. Accordingly, Medicare beneficiaries who enroll in Part D will no longer qualify under traditional PAP eligibility criteria. Part D enrollees will incur cost-sharing obligations (including deductibles and copayments), although many low-income beneficiaries will qualify for subsidies that will reduce or eliminate their financial obligations.¹ Pharmaceutical manufacturers have expressed interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low-income subsidy.

OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws.² We have been asked whether the

anti-kickback statute will be implicated if pharmaceutical manufacturer PAPs³ continue to offer assistance to financially needy Medicare beneficiaries who enroll in Part D by subsidizing their cost-sharing obligations for covered Part D drugs. For the reasons set forth below and consistent with extant OIG guidance, we conclude that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute. However, in the circumstances described in this Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions. In addition, we believe other arrangements described in this Bulletin, if properly structured, may pose reduced risk. Thus, we believe lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.

Given the importance of ensuring continued access to drugs for beneficiaries of limited means and the expedited time frame for implementation of the Part D benefit, we are issuing this Special Advisory Bulletin to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse. This Special Advisory Bulletin draws on the government's prior fraud and abuse guidance and enforcement experience. However, because the Part D benefit has not yet begun, and any

sharing or premium amounts under Part D raise different issues and may require a different analysis. While this Bulletin may provide some useful guidance for other kinds of PAP arrangements, such PAPs are not specifically considered here.

³ For purposes of this Special Advisory Bulletin, a pharmaceutical manufacturer PAP includes any PAP that is directly or indirectly operated or controlled in any manner by a pharmaceutical manufacturer or its affiliates (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)). Moreover, for purposes of an anti-kickback analysis, we would not consider a charitable foundation (or similar entity) formed, funded or controlled by a manufacturer or any of its affiliates (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) to be a *bona fide*, independent charity, because interposition of the entity would not sever the nexus between the patient subsidies and the manufacturer. Indeed, in most cases, the foundation would receive all of its funding from the pharmaceutical manufacturer (or its affiliates) and would provide subsidies only for the manufacturer's products.

assessment of fraud and abuse is necessarily speculative, this Bulletin cannot, and is not intended to, be an exhaustive discussion of relevant risks or beneficial practices.

At the outset, it is important to note the following:

PAPs need not disenroll all Medicare beneficiaries from their existing PAPs to be compliant with the fraud and abuse laws. Enrollment in Part D is voluntary; therefore, existing PAPs may continue to provide free or reduced price outpatient prescription drugs to Medicare beneficiaries who have not yet enrolled in Part D. The Centers for Medicare & Medicaid Services (CMS) anticipates instituting procedures that will help PAPs determine if PAP clients have enrolled in Part D.

Occasional, inadvertent cost-sharing subsidies provided by a pharmaceutical manufacturer PAP to a Part D enrollee should not be problematic under the anti-kickback statute (e.g., where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D).

Nothing in the Part D program or in any OIG laws or regulations prevents pharmaceutical manufacturers or others from providing assistance (e.g., through cash subsidies or free drugs) to uninsured patients. Nothing in this Bulletin impacts programs that assist uninsured patients.

Nothing in this guidance should be construed as preventing pharmacies from waiving cost-sharing amounts owed by a Medicare beneficiary on the basis of a good faith, individualized assessment of the patient's financial need (or failure of reasonable collection efforts), so long as the waiver is neither routine, nor advertised. Financial need-based waivers that meet these criteria have long been permitted.⁴ However, a pharmacy has not waived a cost-sharing amount if the amount has been paid to the pharmacy, in cash or in kind, by a

¹ See 42 CFR 423.782.

² This Bulletin focuses on the application of the Federal anti-kickback statute. Other potential risk areas, including, for example, potential liability under the False Claims Act, 31 U.S.C. 3729–33, or other Federal or State laws, are not addressed here. Moreover, this Bulletin focuses on arrangements that involve pharmaceutical manufacturers directly or indirectly subsidizing Part D cost-sharing amounts. Programs that subsidize Part D premium amounts pose risks under the anti-kickback statute that are not addressed here. Similarly, PAPs established by health plans that subsidize cost

⁴ See, e.g., section 1128A(i)(6)(A) of the Act; OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, August 2002, <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) included a safe harbor specifically incorporating these criteria for waivers of cost-sharing amounts for Part D drugs. Additionally, the safe harbor protects cost-sharing waivers offered to individuals who qualify for the low income subsidy, even if the waivers are routine and do not follow an individualized determination of financial need, provided they are not advertised. See Section 1860D–42 of MMA, codified at 42 U.S.C. 1320a–7b(b)(3)(G).

third party (including, without limitation, a PAP).

II. The Federal Anti-Kickback Statute

The Federal anti-kickback statute, section 1128B(b) of the Social Security Act (the Act),⁵ makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program, including Medicare and Medicaid. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. OIG may also initiate administrative proceedings to exclude a person from Federal health care programs or to impose civil money penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁶

A determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all of the relevant facts and circumstances, including the intent of the parties. For PAPs, the nature, structure, sponsorship, and funding of the particular PAP are necessarily relevant to the analysis.

III. Patient Assistance Programs

As described more fully below, cost-sharing subsidies provided by pharmaceutical manufacturer PAPs pose a heightened risk of fraud and abuse under the Federal anti-kickback statute. However, there are non-abusive alternatives available. In particular, as discussed below, pharmaceutical manufacturers can donate to *bona fide* independent charity PAPs, provided appropriate safeguards exist. Moreover, this Bulletin discusses several other alternatives that may pose a reduced risk of fraud and abuse.

This section addresses in turn: pharmaceutical manufacturer PAPs, independent charity PAPs, manufacturer PAPs that operate “outside of Part D”; “coalition model” PAPs, and bulk replacement programs.

A. Pharmaceutical Manufacturer PAPs

Analytically, pharmaceutical manufacturer PAPs raise two main issues in connection with the Part D program: (i) Whether subsidies they provide can count toward a Part D enrollee’s true out-of-pocket costs (known as the TrOOP); and (ii) whether the subsidies implicate the Federal anti-kickback statute.⁷

As to the first issue, the Part D regulations make clear that beneficiaries may count toward their TrOOP assistance received from any source other than group health plans, other insurers and government funded health programs, and similar third party payment arrangements.⁸ The preamble to the Part D regulations explains that cost-sharing assistance furnished by a PAP, including a manufacturer PAP, will count toward a beneficiary’s TrOOP expenditures, even if the PAP does not comply with the fraud and abuse laws.⁹ This approach relieves beneficiaries of the financial risk of accepting assistance from an entity that may be improperly structured or operated.

As to the second issue, the core question is whether the anti-kickback statute would be implicated if a manufacturer of a drug covered under Part D were to subsidize cost-sharing amounts (directly or indirectly through a PAP) incurred by Part D beneficiaries for the manufacturer’s product. Consistent with our prior guidance addressing manufacturer cost-sharing subsidies in the context of Part B drugs,¹⁰ we believe such subsidies for

Part D drugs would implicate the anti-kickback statute and pose a substantial risk of program and patient fraud and abuse.¹¹ Simply put, the subsidies would be squarely prohibited by the statute, because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product. Where a manufacturer PAP offers subsidies tied to the use of the manufacturer’s products (often expensive drugs used by patients with chronic illnesses), the subsidies present all of the usual risks of fraud and abuse associated with kickbacks, including steering beneficiaries to particular drugs; increasing costs to Medicare; providing a financial advantage over competing drugs; and reducing beneficiaries’ incentives to locate and use less expensive, equally effective drugs.

It is impossible to predict with certainty the way in which abuse may occur in a new benefit program that is not yet operational. The following are illustrative examples of some types of abuse that may occur:

Increased costs to the program. We are concerned that a manufacturer might use beneficiary cost-sharing subsidies, which help beneficiaries meet their TrOOP requirement, to increase the number of beneficiaries using the manufacturer’s product who reach the

from pharmaceutical manufacturer PAPs to subsidize Part B cost-sharing amounts). We note that the cost and utilization management features of the Part D program, while important, do not sufficiently mitigate the risks.

¹¹ Some in the industry have asserted that cost-sharing subsidies for Part D drugs differ from cost-sharing subsidies for Part B drugs so long as the subsidies are given to patients who are in a Part D “coverage gap” (*i.e.*, a benefit period during which the beneficiary pays 100% of the cost of the drugs). To support their position, they contend either that beneficiaries in the coverage gap are functionally “uninsured” or that the situation is comparable to providing free drugs to financially needy beneficiaries so long as no Federal health care program is billed for all or part of the drug, a practice we previously permitted in the context of subsidies for Part B drugs. See OIG Advisory Opinion Nos. 02–13 and 03–3. Under Part D, a “coverage gap” is a period of insurance coverage. See CMS Frequently Asked Question ID 4855, http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=4855 (regarding prescription drug benefit coordination of benefits and TrOOP). During the coverage gap, beneficiaries remain enrolled in their Part D plans and have a continuing obligation to pay Part D premiums; Part D plans continue to receive the monthly per-enrollee direct subsidy from the Medicare program. Moreover, subsidies during the coverage gap are not like furnishing free drugs where no Federal health care program is billed. Sufficient spending during the coverage gap qualifies the beneficiary to reach the catastrophic coverage portion of the Part D benefit, at which point the Medicare program resumes payment for most of the costs of the beneficiary’s drugs. In this regard, the different structures of the Part B and Part D benefits are crucial to the analysis.

⁷ In some cases, a subsidy for Part D cost-sharing obligations provided by a pharmaceutical manufacturer may also implicate the prohibition on offering inducements to beneficiaries, as set forth in section 1128A(a)(5) of the Act, if the subsidy is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier, such as a physician or pharmacy. We have interpreted “provider, practitioner, or supplier” to exclude pharmaceutical manufacturers unless they also own or operate pharmacies, pharmaceutical benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs. See Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, *supra* note 4.

⁸ See 42 CFR 423.100; 42 CFR 423.464; 70 FR 4194, 4239 (January 28, 2005). We note that CMS is the proper agency to address questions about the mechanics of calculating TrOOP. In certain circumstances, knowing improper TrOOP calculations may give rise to liability under the False Claims Act, 31 U.S.C. 3729–33.

⁹ See 70 FR 4194 at 4239.

¹⁰ See, *e.g.*, OIG Advisory Opinion Nos. 02–13 and 03–3 (unfavorable opinions involving proposals

⁵ 42 U.S.C. 1320a–7b(b).

⁶ 42 U.S.C. 1320a–7(b)(7); 42 U.S.C. 1320a–7a(a)(7).

catastrophic benefit in any given coverage year and to hasten the point during the coverage year at which beneficiaries reach the catastrophic benefit. This is of particular import because Medicare will make cost-based payments during the catastrophic coverage benefit.¹² We know from experience that cost-based reimbursement is inherently prone to abuse, including by vendors that sell products reimbursed on a cost basis. Similarly, we are concerned about the use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices. Inflated prices could have a “spillover” effect on the size of direct subsidies, reinsurance payments, and risk corridor payments paid by Medicare to Part D plans in future years,¹³ potentially resulting in higher costs to the Medicare program.

Beneficiary steering and anti-competitive effects. Subsidies provided by traditional pharmaceutical manufacturer PAPs have the practical effect of locking beneficiaries into the manufacturer’s product, even if there are other equally effective, less costly alternatives (and even if the patient’s physician would otherwise prescribe one of these alternatives). Subsidizing Medicare Part D cost-sharing amounts will have this same steering effect. Moreover, as we have previously noted in the Part B context, cost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer’s sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions. We are concerned that pharmaceutical manufacturers may seek improperly to maximize these profits by creating sham “independent” charities to operate PAPs; by colluding with independent charity programs to ensure that the manufacturer’s contributions only or primarily benefit patients using its products (discussed in more detail below); or by manipulating financial need or other eligibility criteria to maximize the number of beneficiaries qualifying for cost-sharing subsidies.

¹² See 42 CFR 423.329. For purposes of calculating payments under catastrophic coverage, the cost of a beneficiary’s drug is based in part on the plan’s negotiated price (*i.e.*, a price that is set by the plan based on negotiations with pharmaceutical manufacturers and pharmacies).

¹³ See 42 CFR 423.329; 42 CFR 423.336.

These risks are necessarily illustrative, not exhaustive, of the potential risks presented by pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts.

Cost-sharing subsidies offered by a pharmaceutical manufacturer PAP to the dispensing supplier differ in two important respects from a provider’s or supplier’s unadvertised, non-routine waiver of cost-sharing amounts based on a patient’s financial need, which has long been permitted. First, the subsidies result in the dispensing supplier receiving full payment for the product and avoiding the risk of non-collection, thus providing the supplier with an economic incentive to favor the subsidized product and a disincentive to recommend a lower-cost alternative, such as a generic. In addition, the availability of PAP assistance is typically advertised and may influence a beneficiary’s choice of product (through the prescribing physician acting on behalf of the beneficiary). Moreover, once a beneficiary is enrolled in a pharmaceutical manufacturer PAP, the beneficiary is effectively locked into using the pharmaceutical manufacturer’s product, since the beneficiary risks losing financial assistance if he or she switches products, even if an equally effective, but less expensive, product would be in his or her best medical interests.

A definitive conclusion regarding whether a particular manufacturer PAP violates the anti-kickback statute would require a case-by-case analysis of all of the relevant facts and circumstances, including the intent of the parties. However, for the reasons noted above, we believe that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts raise substantial concerns under the anti-kickback statute.

B. Independent Charity PAPs

Long-standing OIG guidance makes clear that pharmaceutical manufacturers can effectively contribute to the pharmaceutical safety net by making cash donations to independent, *bona fide* charitable assistance programs.¹⁴

¹⁴ In-kind donations of drugs to independent charity PAPs pose additional risks not yet directly addressed in prior OIG guidance, and we have insufficient experience with them to offer detailed guidance here. While in-kind donations have the potential benefit of increasing the value of donations (because marginal costs of drugs are generally low), they also have the effect of creating a direct correlation between the donation and use of a particular donor’s product, thereby weakening important safeguards of an independent charity PAP arrangement. Moreover, there would appear to be difficult accounting and valuation issues raised by the use of in-kind product to subsidize Part D

Under a properly structured program, donations from a pharmaceutical manufacturer to an independent, *bona fide* charity that provides cost-sharing subsidies for Part D drugs should raise few, if any, anti-kickback statute concerns, so long as:

(i) Neither the pharmaceutical manufacturer nor any affiliate of the manufacturer (including, without limitation, any employee, agent, officer, shareholder, or contractor (including, without limitation, any wholesaler, distributor, or pharmacy benefits manager)) exerts any direct or indirect influence or control over the charity or the subsidy program;

(ii) The charity awards assistance in a truly independent manner that severs any link between the pharmaceutical manufacturer’s funding and the beneficiary (*i.e.*, the assistance provided to the beneficiary cannot be attributed to the donating pharmaceutical manufacturer);

(iii) The charity awards assistance without regard to the pharmaceutical manufacturer’s interests and without regard to the beneficiary’s choice of product, provider, practitioner, supplier, or Part D drug plan;

(iv) The charity provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner; and ¹⁵

(v) The pharmaceutical manufacturer does not solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products.¹⁶

cost-sharing obligations, both for purposes of calculating TrOOP and for purposes of determining the amount of in-kind drug that equals the Part D cost-sharing amount owed.

¹⁵ We recognize that what constitutes an appropriate determination of financial need may vary depending on individual patient circumstances. We believe that independent charity PAPs should have flexibility to consider relevant variables beyond income. For example, PAPs may choose to consider the local cost of living; a patient’s assets and expenses; a patient’s family size; and the scope and extent of a patient’s medical bills.

¹⁶ We have previously approved a *bona fide* independent charity PAP arrangement that included only limited reporting of *aggregate* data to donors in the form of monthly or less frequent reports containing *aggregate* data about the number of all applicants for assistance in a disease category and the number of patients qualifying for assistance in that disease category. See OIG Advisory Opinion No. 02–1. No individual patient information may be conveyed to donors. Moreover, neither patients nor donors may be informed of the donation made to the PAP by others, although, as required by Internal Revenue Service regulations, the PAP’s annual report and a list of donors may be publicly available. See OIG Advisory Opinion No. 04–15. Reporting of data that is not in the aggregate or that is patient specific would be problematic, as would reporting of any data, whether or not in the

Simply put, the independent charity PAP must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices.¹⁷

We recognize that some *bona fide* independent charities reasonably focus their efforts on patients with particular diseases (such as cancer or diabetes) and that some of these charities permit donors to earmark their contributions generally for support of patients with a specific disease. In general, the fact that a pharmaceutical manufacturer's donations are earmarked for one or more broad disease categories should not significantly raise the risk of abuse. However, we are concerned that, in some cases, charities may artificially define their disease categories so narrowly that the earmarking effectively results in the subsidization of one (or a very few) of donor's particular products. For example, we would be concerned if disease categories were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs, rather than by diagnoses or broadly recognized illnesses or diseases. This type of arrangement would present an elevated risk of fraud and abuse because of the increased likelihood that the PAP would function as an improper conduit for manufacturers to provide funds to patients using their specific drugs. To avoid this risk, pharmaceutical manufacturers should not influence, directly or indirectly, the identification of disease or illness categories,¹⁸ and pharmaceutical manufacturers should limit their earmarked donations to PAPs that define categories in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products.¹⁹

aggregate, related to the identity, amount, or nature of subsidized drugs.

¹⁷ For further guidance on establishing compliant independent charity PAPs, see OIG Advisory Opinion Nos. 04–15, 02–1, 98–17, and 97–1 (favorable opinions issued to *bona fide*, independent charities that accept industry funding).

¹⁸ Nothing in this Bulletin should be construed as preventing a charity from obtaining educational materials from donors that the donors generally make available to practitioners or the general public (e.g., clinical information about drug products).

¹⁹ We recognize that, in rare circumstances, there may only be one drug covered by Part D for the diseases in a particular category or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the diseases in a particular category. In these unusual circumstances, the fact that a disease category only includes one drug or manufacturer would not, standing alone, be determinative of an anti-kickback statute violation. Such a determination could only be made on a case-by-case basis after examining all of the applicable facts and

C. PAPs Operating Outside Part D

CMS has issued guidance stating that PAPs may elect to provide free drugs to financially needy Medicare Part D enrollees outside the Part D benefit.²⁰ In these circumstances, the beneficiary obtains drugs without using his or her Part D insurance benefit. Beginning when a beneficiary's assistance under a PAP became effective, no claims for payment for any covered outpatient prescription drug provided outside of the Part D benefit may be filed with a Part D plan or the beneficiary, and the assistance must not count toward the beneficiary's TrOOP or total Part D spending for any purpose. For the reasons noted in connection with pharmaceutical manufacturer PAPs discussed above, PAPs that provide assistance outside the Part D benefit only during the coverage gap (*i.e.*, "wrapping around" the Part D benefit) pose a heightened risk of abuse. However, while it is difficult to assess the application of the fraud and abuse laws to PAPs that operate outside Part D absent a specific set of facts, it would appear that PAPs that furnish free outpatient prescription drugs entirely outside the Part D benefit pose a reduced risk under the anti-kickback statute, provided that:

(i) The PAP includes safeguards that ensure that Part D plans are notified that the drug is being provided outside the Part D benefit so that no payment is made for the subsidized drug by any Part D plan and no part of the costs of the subsidized drug is counted toward any beneficiary's TrOOP;

(ii) The PAP provides assistance for the whole Part D coverage year (or the portion of the coverage year remaining after the beneficiary first begins receiving the PAP assistance);²¹

(iii) The PAP assistance remains available even if the beneficiary's use of the subsidized drug is periodic during the coverage year;

(iv) The PAP maintains accurate and contemporaneous records of the

circumstances, including the intent of the parties. We note that it would be important for the PAP program to cover additional products or manufacturers as they become available.

²⁰ See CMS Frequently Asked Question ID 6153, http://questions.cms.hhs.gov/cgi-bin/cms_hhs.cgi/php/enduser/std_adp.php?p_faqid=6153 (regarding PAPs providing assistance with Part D drug costs to Part D enrollees outside of the Part D benefit and without counting towards TrOOP).

²¹ We note that our position that PAPs operating outside the Part D benefit should provide assistance for the remainder of the coverage year is consistent with our observation in several advisory opinions that manufacturers "may provide free drugs to financially needy beneficiaries, so long as no Federal health care program is billed for all or part of the drugs." OIG Advisory Opinion Nos. 02–13 and 03–3.

subsidized drugs to permit the Government to verify the provision of drugs outside the Part D benefit;

(v) Assistance is awarded based on reasonable, uniform, and consistent measures of financial need and without regard to the providers, practitioners, or suppliers used by the patient or the Part D plan in which the patient is enrolled; and

(vi) The arrangement complies with any then-existing guidance from CMS.

In addition, to promote quality of care, we believe it would be important for PAPs that provide free drugs outside the Part D benefit to coordinate effectively with Part D plans so that the plans can undertake appropriate drug utilization review and medication therapy management program activities.

D. "Coalition Model" PAPs

We are aware of nascent efforts by some in the industry to develop arrangements through which multiple pharmaceutical manufacturers would join together to offer financially needy Part D enrollees a card or similar vehicle that would entitle the enrollees to subsidies of their cost-sharing obligations for the manufacturers' products, typically in the form of discounts off the negotiated price otherwise available to the enrollee under his or her Part D plan. It is premature to offer definitive guidance on these evolving programs. Although these programs would operate so that the manufacturers effectively underwrite only the discounts on their own products, we observe that the risk of an illegal inducement potentially may be reduced if: (i) The program contains features that adequately safeguard against incentives for card holders to favor one drug product (or any one supplier, provider, practitioner, or Part D plan) over another; (ii) the program includes a large number of manufacturers, including competing manufacturers and manufacturers of both branded and generic products, sufficient to sever any nexus between the subsidy and a beneficiary's choice of drug; and (iii) each participating pharmaceutical manufacturer offers subsidies for *all* of its products that are covered by *any* Part D plan formulary. Other safeguards may also be needed to reduce the risk of an improper inducement. Moreover, a program under which Part D enrollees pay a portion of their drug costs out-of-pocket would tend to reduce the risk of abuse by preserving the beneficiary's incentive to locate and purchase equally effective, lower cost drugs.

IV. Bulk Replacement Models

Bulk replacement²² or similar programs, pursuant to which pharmaceutical manufacturers (or their affiliated PAPs) provide in-kind donations in the form of free drugs to pharmacies, health centers, clinics, and other entities that dispense drugs to qualifying uninsured patients, are different from traditional PAPs that provide assistance directly to patients. These programs potentially implicate the Federal anti-kickback statute if the free drugs are given to a recipient that is in a position to generate Federal health care program business for the donor manufacturer. Whether a particular bulk replacement program complies with the fraud and abuse laws would require a case-by-case analysis. In undertaking any analysis, we would consider, among other factors, how the program is structured and whether there are safeguards in place: (i) To protect Federal health care program beneficiaries from being steered to particular drugs based on the financial interests of their health care providers or suppliers; (ii) to protect the Federal health care programs from increased program costs; and (iii) to ensure that bulk replacement drugs are not improperly charged to Federal health care programs. Additionally, bulk replacement as a means of subsidizing only the Medicare Part D cost-sharing amount potentially raises substantial risks related to accounting for the amount of replacement drug that would be equivalent to the cost-sharing amount owed by the beneficiary; properly attributing that amount to specific beneficiaries; and properly calculating TrOOP.

V. Transitioning From Existing Pharmaceutical Manufacturer PAPs

OIG is mindful of the importance of a smooth, effective transition for beneficiaries who are currently participating in pharmaceutical manufacturer PAPs and elect to enroll in Medicare Part D. While most such enrollees are likely to qualify for the low-income subsidies available under Part D, we are concerned that there may not be sufficient independent charity PAPs available before the January 1, 2006 start date of the Part D program to accommodate beneficiaries of limited means who may need an alternative PAP arrangement. We recognize the importance of not unnecessarily burdening or alarming beneficiaries. We believe that manufacturers will play an important role in ensuring an effective transition.

With respect to pharmaceutical manufacturer PAPs that are in existence prior to the date of publication of this Special Advisory Bulletin, during the initial calendar year of the Part D benefit, OIG will take into consideration in exercising its enforcement discretion with respect to administrative sanctions arising under the anti-kickback statute whether the PAP is taking prompt, reasonable, verifiable, and meaningful steps to transition patients who enroll in Part D to alternative assistance models, such as independent charities.

In addition to taking steps to transition beneficiaries to other programs, pharmaceutical manufacturer PAPs can reduce their fraud and abuse exposure by taking one or more of the following steps: (i) Adjusting financial need criteria to reflect the lower drug costs incurred by Part D enrollees (*i.e.*, liability for premiums and cost-sharing amounts only, instead of the total cost of the drugs); (ii) where possible, subsidizing other drugs in the same class as the manufacturer's products covered by the PAP if a beneficiary's physician prescribes an alternate product; and (iii) checking CMS eligibility files, to the extent available, on a reasonably regular basis to determine whether PAP patients have enrolled in Part D and should be transitioned to other assistance programs. Occasional, inadvertent cost-sharing subsidies provided to a Part D enrollee should not be problematic (*e.g.*, where, despite due diligence, a pharmaceutical manufacturer PAP does not know and should not have known that a beneficiary has enrolled in Medicare Part D). Notwithstanding a pharmaceutical manufacturer's compliance with the foregoing, the Government will take enforcement action in cases where there is evidence of unlawful intent.

The potential variability of PAPs, the fact that the Part D program is not yet operational, and the fact that it is not possible to predict all future or potential fraud and abuse schemes with certainty, make it difficult to provide comprehensive general guidance on the application of the anti-kickback statute to PAPs for Part D enrollees at this time. We intend to monitor the situation closely and may issue further guidance, if needed. Nothing in this Bulletin should be construed as precluding any form of lawful assistance not described in this Bulletin.

VI. OIG Advisory Opinion Process

OIG has an advisory opinion process that is available to individuals and entities, including pharmaceutical manufacturers, that want assurance that

they will not run afoul of the fraud and abuse laws.²² OIG advisory opinions are written opinions that are legally binding on OIG, the Department, and the party that requests the opinion. To obtain an opinion, the requesting party must submit a detailed, written description of its existing or proposed business arrangement. The length of time that it takes for OIG to issue an opinion varies based upon a number of factors, including the complexity of the arrangement, the completeness of the submission, and how promptly the requestor responds to requests for additional information. Further information about the process, including frequently asked questions, can be found on the OIG Web page at <http://oig.hhs.gov/fraud/advisoryopinions.html>.

The Office of Inspector General (OIG) was established at the Department of Health and Human Services by Congress in 1976 to identify and eliminate fraud, abuse, and waste in the Department's programs and to promote efficiency and economy in departmental operations. OIG carries out this mission through a nationwide program of audits, investigations, and inspections. The Health Care Fraud and Abuse Control Program, established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), authorized OIG to provide guidance to the health care industry to prevent fraud and abuse and to promote the highest level of ethical and lawful conduct. To further these goals, OIG issues Special Advisory Bulletins about industry practices or arrangements that potentially implicate the fraud and abuse authorities subject to enforcement by OIG.

Daniel R. Levinson,
Inspector General.

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DEPARTMENT OF HOMELAND SECURITY

[DHS-2005-0054]

Office of State and Local Government Coordination and Preparedness; SAFER Grant Program

AGENCY: Office of State and Local Government Coordination and Preparedness, DHS.

ACTION: Notice and request for comment.

SUMMARY: Pursuant to the Paperwork Reduction Act, the Department of Homeland Security (DHS) solicited comments on the proposed collection of information in connection with the Staffing for Adequate Fire and Emergency (SAFER) Grant Application.

²² Section 1128D(b) of the Act; 42 CFR part 1008.

EXHIBIT B

recommended by a urologist based on current standard of care, before consideration of PROGENSA PCA3 ASSAY results. A PCA3 score <25 is associated with a decreased likelihood of a positive biopsy. Prostatic biopsy is required for diagnosis of cancer. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for PROGENSA PCA3 ASSAY (U.S. Patent No. 7,008,765) from The Johns Hopkins University & The Stichting Katholieke Universiteit, The University Medical Centre Nijmegen, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated February 1, 2013, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of PROGENSA PCA3 ASSAY represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for PROGENSA PCA3 ASSAY is 936 days. Of this time, 383 days occurred during the testing phase of the regulatory review period, while 553 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective or if an exemption is not required, the date an institutional review board under section 520(g)(3) of the FD&C Act (21 U.S.C. 360j(g)(3)) approved the clinical investigation of the device in humans:* July 24, 2009. FDA has confirmed the applicant's claim that no investigational device exemption (IDE) was required under section 520(g) of the FD&C Act for human tests to begin. Institutional review board (IRB) approval was required under section 520(g)(3) of the FD&C Act and became effective on July 24, 2009.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* August 10, 2010. FDA has verified the applicant's claim that the premarket approval application (PMA) for PROGENSA PCA3 ASSAY (PMA 100033) was initially submitted August 10, 2010.

3. *The date the application was approved:* February 13, 2012. FDA has verified the applicant's claim that PMA

P100033 was approved on February 13, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 745 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 29, 2014. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 26, 2014. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to <http://www.regulations.gov>, Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on <http://www.regulations.gov> may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 27, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–12562 Filed 5–29–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This Supplemental Bulletin updates the OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees that published in the **Federal Register** on November 22, 2005 (70 FR 70623).

SUPPLEMENTARY INFORMATION:

I. Introduction

Patients who cannot afford their cost-sharing obligations for prescription drugs may be able to obtain financial assistance through a patient assistance program (PAP). PAPs have long provided important safety net assistance to such patients, many of whom have chronic illnesses and high drug costs. Many PAPs also present a risk of fraud, waste, and abuse with respect to Medicare and other Federal health care programs. We issued a Special Advisory Bulletin regarding PAPs in 2005¹ (the 2005 SAB) in anticipation of questions likely to arise in connection with the Medicare Part D benefit. In the 2005 SAB, we addressed different types of PAPs and stated that we believed lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary drugs.² We also noted in the 2005 SAB that we could only speculate on fraud and abuse risk areas, because the Part D benefit had not yet begun. This Supplemental Special Advisory Bulletin (Supplemental Bulletin) is based on experience we have gained in the intervening years; it is not intended to replace the 2005 SAB, nor does it replace other relevant guidance, such as the 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries.³

We continue to believe that properly structured PAPs can help Federal health care program beneficiaries. This Supplemental Bulletin provides additional guidance regarding PAPs operated by independent charities (Independent Charity PAPs) that provide cost-sharing assistance for

¹ OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 FR 70623 (Nov. 22, 2005), available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf>.

² The 2005 SAB focused on PAPs under the then-upcoming Part D program, but the guidance also referenced co-payment assistance programs for drugs covered under Medicare Part B. Although these Medicare programs differ, and the types of PAPs may differ, the principles set forth in the 2005 SAB and herein apply regardless of which Federal health care program (as defined in section 1128B(f) of the Social Security Act (the Act)) covers the drugs.

³ The 2002 OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries is available at: <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

prescription drugs. To address some of the specific risks that have come to our attention in recent years, this guidance discusses problematic features of PAPs with respect to the anti-kickback statute, section 1128B(b) of the Act,⁴ and the provision of the Civil Monetary Penalties Law prohibiting inducements to Medicare and Medicaid beneficiaries (Beneficiary Inducements CMP), section 1128A(a)(5) of the Act.⁵ Other potential risk areas, including, for example, potential liability under the False Claims Act, 31 U.S.C. 3729–33, or other Federal or State laws, are not addressed here.

II. The Anti-Kickback Statute and the Beneficiary Inducements CMP

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program, including Medicare and Medicaid. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to give or obtain money for the referral of services or to induce further referrals. Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to 5 years, or both. OIG may also initiate administrative proceedings to exclude a person from Federal health care programs or to impose civil monetary penalties for kickback violations under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁶

Two remunerative aspects of PAP arrangements require scrutiny under the anti-kickback statute: donor contributions to PAPs (which can also be analyzed as indirect remuneration to patients) and PAPs’ grants to patients. If a donation is made to a PAP to induce the PAP to recommend or arrange for the purchase of the donor’s federally reimbursable items, the statute could be violated. Similarly, if a PAP’s grant of

financial assistance to a patient is made to influence the patient to purchase (or to induce the patient’s physician to prescribe) certain items, the statute also could be violated. A determination regarding whether a particular arrangement violates the anti-kickback statute requires an individualized evaluation of all of the relevant facts and circumstances, including the parties’ intent. For PAPs, the nature, structure, sponsorship, and funding of the particular PAP are factors relevant to the analysis.

The Beneficiary Inducements CMP provides for the imposition of civil monetary penalties against any person that offers or transfers remuneration to a Medicare or State health care program (as defined under section 1128(h) of the Act) beneficiary that the benefactor knows or should know is likely to influence the beneficiary to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. OIG may initiate administrative proceedings to seek such CMPs and exclude such person from the Federal health care programs. A subsidy for cost-sharing obligations provided by a pharmaceutical manufacturer through a PAP may implicate the Beneficiary Inducements CMP, if the subsidy is likely to influence a Medicare or State health care program beneficiary’s selection of a particular provider, practitioner, or supplier, such as by making eligibility dependent on the patient’s use of certain prescribing physicians or certain pharmacies to dispense the drugs.

III. Independent Charity PAPs

Longstanding OIG guidance, including the 2005 SAB, makes clear that pharmaceutical manufacturers can effectively contribute to the safety net by making cash donations to independent, *bona fide* charitable assistance programs. The 2005 SAB sets forth a number of factors that we continue to believe are fundamental to a properly structured Independent Charity PAP. See 70 FR 70626. Many of these factors relate to the independence of the charity, as discussed further below. In this Supplemental Bulletin, we expand on our previous guidance in that regard, focusing on three areas: Disease funds, eligible recipients, and the conduct of donors.

A. Disease Funds

As we explained in the 2005 SAB, we recognize that *bona fide* independent charities may reasonably focus their

efforts on patients with particular diseases (such as cancer or diabetes) and that, in general, the fact that a pharmaceutical manufacturer’s donations to an independent charity are earmarked for one or more broad disease funds should not significantly raise the risk of abuse. At the time, however, we also expressed our concern that, in some cases, charities might define their disease funds so narrowly that the earmarking effectively results in a donor’s subsidization of its own products. Over the past several years, we have become aware that some Independent Charity PAPs are, in fact, establishing narrowly defined disease funds and covering a limited number of drugs within those funds. To address this development, we discuss and expand on some of the safeguards that we originally set forth in the 2005 SAB to reduce the risk of abuse. We reiterate here that an Independent Charity PAP must not function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries’ drug choices.

One of the points we made in the Independent Charity PAPs section of the 2005 SAB was that pharmaceutical manufacturers and their affiliates should not exert any direct or indirect influence or control over the charity or its assistance program. We also stated that donors should not influence the identification of disease funds⁷ and that we would be concerned if disease funds were defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. These were merely examples—not an exclusive list—of improperly narrow approaches to defining disease funds. For example, we also are concerned about disease funds defined by reference to the stages of a particular disease, the type of drug treatment, and any other ways of narrowing the definition of widely recognized disease states. A charity with narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors’ products.⁸

⁷ The 2005 SAB used the term “disease categories.” Our experience since 2005 suggests that the term “disease fund” is more accurate in this context.

⁸ This is true even if the charity has obtained a favorable advisory opinion, because favorable opinions related to PAPs typically are based upon the charity’s certifications that: (1) No donor or affiliate of any donor has exerted or will exert any

Continued

⁴ 42 U.S.C. 1320a–7b(b).

⁵ 42 U.S.C. 1320a–7a(a)(5).

⁶ 42 U.S.C. 1320a–7(b)(7) and 42 U.S.C. 1320a–7a(a)(7).

We also are increasingly concerned about Independent Charity PAPs that choose to establish or operate disease funds that limit assistance to a subset of available products. Through our advisory opinion process, we have seen Independent Charity PAPs seeking to cover few drugs, such as by covering copayments only for expensive or specialty drugs. We are concerned that funds limited in this manner may not be beneficial to patients or Federal health care programs. Beneficiaries should not be tied to a particular product, or to a subset of available products, to receive or continue their assistance. Although we recognize that a patient prescribed an expensive drug may have a greater need for financial assistance than a patient prescribed a less expensive alternative, we are concerned that limiting PAP cost-sharing support to expensive products may steer patients in a manner that is costly to Federal health care programs and may even facilitate increases in drug prices. Moreover, whether a drug is “expensive” is a relative question that depends, in part, on the financial resources of the consumer; even a generic drug can be expensive for some patients. Finally, limiting assistance to certain drugs may steer patients away from potentially more beneficial products because assistance is available for one treatment and not another. Consequently, a fund will be subject to more scrutiny if it is limited to a subset of available products, rather than all products approved by the Food and Drug Administration (FDA) for treatment of the disease state(s) covered by the fund or all products covered by the relevant Federal health care program when prescribed for the treatment of the disease states (including generic or bioequivalent drugs).⁹

direct or indirect influence or control over the charity or any of the charity's programs; (2) the charity will define its disease funds in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of available products; and (3) the charity's disease funds will not be defined by reference to specific symptoms, severity of symptoms, or the method of administration of drugs. If the arrangement does not in practice comport with the facts presented in the advisory opinion, then the arrangement is not protected by the opinion. All of our advisory opinions are available on the OIG Web site at: <http://oig.hhs.gov/compliance/advisory-opinions/index.asp>.

⁹ An Independent Charity PAP is not required to provide assistance for drugs prescribed off-label. However, we would expect a truly independent charity to treat all its funds equally. Thus, if the Independent Charity PAP offered assistance for all drugs covered by Medicare in Fund A, but limited assistance offered for Fund B to FDA-approved uses, the funds could be subject to scrutiny to determine whether either coverage determination was made to benefit a donor.

The 2005 SAB acknowledged that, in rare circumstances, there may be only one drug covered by Part D for the disease(s) in a particular disease fund or only one pharmaceutical manufacturer (including its affiliates) that makes all of the Part D covered drugs for the disease(s) in a particular disease fund. The 2005 SAB noted that, in these unusual circumstances, the fact that a disease fund includes only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an anti-kickback statute violation. A determination of an anti-kickback statute violation can be made only on a case-by-case basis after examining the applicable facts and circumstances, including the intent of the parties. Notwithstanding the need for an individualized analysis, a disease fund that covers only a single product, or the products made or marketed by only a single manufacturer that is a major donor to the fund, will be subject to scrutiny. When determining whether an anti-kickback violation occurred, we would consider, among other factors, whether the disease fund in question appears to be narrowly defined in a manner that favors any of the fund's donors.

While we understand that many charities have limited resources and seek to use them to assist patients with the greatest financial need, assessing a patient's financial need is a separate concern from determining which drugs to include in a disease fund. Narrowly defining disease funds or limiting disease funds to provide assistance only for expensive drugs can result in steering patients to the drugs for which assistance is available. This type of steering increases the likelihood that the donors could use the PAPs as improper conduits to provide a subsidy to patients who use the donors' own products. This potentially increases costs to the Federal health care programs in cases where a lower cost, equally effective drug is available. Moreover, the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support.

In short, disease funds should be defined in accordance with widely recognized clinical standards and in a manner that covers a broad spectrum of products; disease funds should not be defined for the purpose of limiting the drugs for which the Independent Charity PAP provides assistance.

B. Eligible Recipients

It has come to our attention that some Independent Charity PAPs have started operating, or seek to operate, funds that provide financial assistance only to Federal health care program beneficiaries. We do not believe that the mere fact that a fund serves only Federal health care program beneficiaries increases risk to the Federal health care programs. In fact, we issued a favorable advisory opinion to an Independent Charity PAP that intended to develop a fund to serve only Medicare beneficiaries.¹⁰ The safeguards regarding defining disease funds and recipient eligibility described in the 2005 SAB and in this Supplemental Bulletin, when properly implemented, should sufficiently protect Federal health care programs.

Regardless of whether a fund is available to all patients or is limited to Federal health care program beneficiaries, the Independent Charity PAP must determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner. Some Independent Charity PAPs base their eligibility criteria on the poverty guidelines, which take into account family size, for determining financial need. As we explained in the 2005 SAB, Independent Charity PAPs also have the flexibility to consider relevant variables beyond income. Other variables Independent Charity PAPs may choose to consider, for example, are the local cost of living and the scope and extent of a patient's total medical bills. We are not recommending or requiring any particular method for assessing financial need. We do, however, want to emphasize that the cost of the particular drug for which the patient is applying for assistance is not an appropriate stand-alone factor in determining individual financial need; it is likely one of many obligations that affects the patient's financial circumstances. We also note that generous financial need criteria, particularly when a fund is limited to a subset of available drugs or the drugs of a major donor, could be evidence of intent to fund a substantial part of the copayments for a particular drug (or drugs) for the purpose of inducing the use of that drug (or those drugs), rather than for the purpose of supporting financially needy patients diagnosed with a particular disease.

¹⁰ See Modification of OIG Advisory Opinion 07-06, available at: http://oig.hhs.gov/fraud/docs/advisoryopinions/2011/AdvOpn07-06_mod.pdf.

C. Conduct of Donors

Thus far, this Supplemental Bulletin has focused on the conduct of Independent Charity PAPs. Similarly, when we have issued favorable advisory opinions regarding Independent Charity PAPs, the focus has been on the charities that requested the opinions—not the donors.¹¹ In requesting an opinion, a charity certifies to actions it will take to ensure the independence of the PAP from the donors. The charity is not in a position to certify as to the actions of the donors with parties outside the arrangement. For example, an advisory opinion issued to an independent charity regarding the PAP it operates typically states that the charity has certified that it will provide donors only with reports including data such as the aggregate number of applicants for assistance, the aggregate number of patients qualifying for assistance, and the aggregate amount disbursed from the fund during that reporting period. Thus, the charity would not give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP. The procedures described in these certifications are a critical safeguard and a material fact upon which we have relied in issuing favorable advisory opinions regarding Independent Charity PAPs. These opinions do not address actions by donors to correlate their funding of PAPs with support for their own products. Such actions may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute.

IV. Conclusion

OIG continues to believe that properly structured, Independent Charity PAPs provide a valuable resource to financially needy patients. We also believe that Independent Charity PAPs raise serious risks of fraud, waste, and abuse if they are not sufficiently independent from donors. This Supplemental Bulletin reiterates and amplifies our guidance, based on practices and trends we have seen in the industry. We recognize that some charitable organizations with PAPs have received favorable advisory opinions

that may include features that are discouraged in this Supplemental Bulletin. We are writing to all Independent Charity PAPs that have received favorable opinions to explain how we intend to work with them to ensure that approved arrangements are consistent with our guidance. We anticipate that some opinions will need to be modified. We will post any such modifications on our Web site with the original opinions, consistent with our current practice. Favorable advisory opinions will continue to protect the arrangements described in the opinions until we issue any final notice of modification or termination to the requestors of those opinions. It is our intent that there be no disruption of patient care during this process. Should donors or PAPs continue to have questions about the structure of a particular organization or transaction, the OIG Advisory Opinion process remains available. Information about the process may be found at: <http://oig.hhs.gov/faqs/advisory-opinions-faq.asp>.

Dated: May 16, 2014.

Daniel R. Levinson,
Inspector General.

[FR Doc. 2014–11769 Filed 5–29–14; 8:45 am]

BILLING CODE 4152–01–P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS–2013–0065]

Agency Information Collection Activities: Submission for Review; Information Collection Request for the Department of Homeland Security (DHS), Science and Technology, National Capital Region Secure Delivery Technology Program

AGENCY: Science and Technology Directorate, DHS.

ACTION: 30-Day notice and request for comment.

SUMMARY: The Department of Homeland Security (DHS), Science & Technology Directorate (S&T) invites the general public to comment on data collection forms for the National Capital Region (NCR) Secure Delivery Technology program. This is a new Paper Reduction Act collection without an OMB control number. Secure Delivery Technology is responsible for improving the efficiency and effectiveness of deliveries to General Services Administration (GSA) facilities in the NCR.

Information collected by Federal Protective Service (FPS) personnel to ensure secured deliveries in the NCR

includes the delivery driver's name and license number. The information collected is used by FPS personnel to verify the identity of the driver at the delivery central screening facility and final destination locations, along with providing an auditable trail for post-delivery analysis should an event occur that requires forensics.

DHS invites interested persons to comment on the "National Capital Region Secure Delivery Technology Driver Log" form and instructions (hereinafter "Forms Package") for the S&T NCR Secure Delivery Technology. Interested persons may receive a copy of the Forms Package by contacting the DHS S&T PRA Coordinator. This notice and request for comments is required by the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35).

DATES: Comments are encouraged and will be accepted until June 30, 2014.

ADDRESSES: Interested persons are invited to submit comments, identified by docket number DHS–2013–0065, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Please follow the instructions for submitting comments.

- **Email:** Jonathan.Mcentee@hq.dhs.gov. Please include docket number DHS–2013–0065 in the subject line of the message.

- **Mail:** Science and Technology Directorate, ATTN: National Capital Region Secure Delivery Technology Program, 245 Murray Drive, Mail Stop 0202, Washington, DC 20528.

FOR FURTHER INFORMATION CONTACT: Jonathan Mcentee, Jonathan.Mcentee@hq.dhs.gov, 202–254–6139. (Not a toll free number).

SUPPLEMENTARY INFORMATION: The Department is committed to improving its information collection and urges all interested parties to suggest how these materials can further reduce burden while seeking necessary information under the Paper Reduction Act.

DHS is particularly interested in comments that:

- (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

- (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- (3) Suggest ways to enhance the quality, utility, and clarity of the information to be collected; and

- (4) Suggest ways to minimize the burden of the collection of information

¹¹ An advisory opinion has no application to, and cannot be relied upon by, any individual or entity other than the requestor of the opinion. Thus, a donor is not protected by an advisory opinion issued only to the entity to which it donates. See section 1128D(b)(4)(A) of the Act (42 U.S.C. 1320a–7d(b)(4)(A)); 42 CFR 1008.53.

EXHIBIT C

BARRON'S

FEATURE

Too Close for Comfort?

By Bill Alpert October 19, 2013

Off-duty cops secured the meeting rooms at the Gaylord Texan Resort last month, as the Chronic Disease Fund held its yearly conference at the Dallas-area hotel. Days before, the medical charity had canceled the registrations of some would-be attendees and refunded their \$1,500 donations. The uninvited then got threatening lawyers' letters from [Questcor Pharmaceuticals](#), a drug company that's been a backer of the charity and a bug zapper for short sellers.

Questcor's letters said the barred guests must have bought tickets for the charity's fundraiser and conference to get nonpublic information and manipulate Questcor stock (ticker: QCOR). Those letters, which several Wall Street recipients showed to *Barron's*, told the interlopers to prepare for litigation and to stop contacting the Chronic Disease Fund and its affiliates.

How Questcor learned the registrants' identities is a mystery that neither it nor the charity would explain. The Plano, Texas-based CDF has quickly become one of the country's largest medical charities, its annual receipts surpassing those of better-known groups such as the Susan G. Komen Foundation, which is dedicated to the treatment of breast cancer, or the March of Dimes, which focuses on preventing birth defects. Regulatory filings suggest that Questcor and the CDF owe some of their success to one another.

From 2007 through 2012, the Chronic Disease Fund's tax returns show that it pulled in donations of more than \$900 million, mostly from drug companies like Questcor. The CDF has made a rich man of the charity's founder and president—46-year-old Mike Banigan. Over the same stretch, the CDF paid more than \$35 million for "data-processing" services to a firm that's one of many health-care companies that share offices with the charity and are owned by Banigan. In a section of its 2012 return not shown on its Website, the charity says that last year it bought the data-processing business outright from a Banigan-related trust, for an \$18 million lump sum, plus monthly payments of \$1 million that could add significantly to his take.

The Chronic Disease Fund is the largest of a half-dozen nonprofit "patient-assistance programs" that have emerged in recent years to help patients

President Obama's health-care law will expand the ranks of those with health insurance, but that may also increase the number of those enrolled in high-deductible health plans. Co-pay-assistance programs were pioneered by charities like the National Organization for Rare Disorders to improve access to expensive new therapies that can be the only effective treatments for some rare cancers and other dire illnesses.

CDF's Website shows that it works with numerous drug makers, from [Roche's](#) (ROG.Switzerland) Genentech to [Novartis](#) (NVS), but few companies would seem to need its co-pay programs as much as Questcor. The Anaheim, Calif., company's only marketed product, Acthar, is a 60-year-old, naturally derived substance that it acquired in 2001, raised in price by 1,000% and now sells mostly for illnesses that can also be treated with synthetic steroids like prednisone at 1/100th the price of a \$6,000 Acthar injection. A risk for Questcor is that doctors and patients would abandon Acthar for generic alternatives without the CDF programs that defray the thousand-dollar co-pays.

Questcor spokesperson Janine McCargo said in an e-mail that the company's management is "disinclined to do interviews" and prefers to "let results themselves prove or disprove theories."

Questcor's collaboration with the CDF is one of many savvy moves in the past six years that helped lift its shares from pennies apiece to a recent price of \$65.80. As shown in the chart "Percentage of Questcor's Gross Sales," Questcor also has increased Acthar sales in government-funded channels like the military health-care program Tricare, as well as Medicare and Medicaid.



It's easy to see why some folks like Questcor's stock. The company has grown sales and earnings lately at an annual rate above 60%. Still, the shares trade at less than 16 times the trailing 12 months' earnings of \$4.17. Management returns cash to shareholders through buybacks and a recently raised dividend that amounts to a 2% yield. But it's also easy to see why some curmudgeons have shorted 25% of Questcor's free-trading float. Questcor has disclosed that its promotional practices have been under investigation since 2012 by federal prosecutors in Philadelphia, with whom the company's cooperating. Acthar sales could also take a hit from new initiatives to curb the high-priced drug's use within Tricare and Medicare. To date, the shorts have paid a big price for their skepticism: the stock has risen 4,000% in the past six years. *Barron's* was among the skeptics ("[Medical Marvel](#)," Feb. 7, 2011).

As successful as Questcor has been at helping patients obtain Acthar, the co-

the CDF displays an advisory letter on its Website (cdfund.org) from the Office of the Inspector General of the Department of Health and Human Services, which discusses whether the financing of the co-pay program by drug companies constitutes kickbacks to induce doctors and patients to utilize drugs that are unnecessary or more expensive than equivalents. The OIG's September 2006 advisory letter said the agency wouldn't challenge the CDF's program, as long as drug-company donors didn't influence the charity's choice of targeted diseases and a drug maker's contributions weren't earmarked for its own products.

How well the CDF has abided by those commitments is a fair question, given that eight of the 37 disease states for which the CDF Website says it is enrolling patients are diseases for which Acthar is the only drug on the charity's list of approved therapies—even though branded and generic alternatives for those diseases are on the market.

Questcor spokesperson McCargo says the company donated \$3.1 million to the CDF for co-pays in the June 2013 quarter. If patients averaged a 10% co-pay, that would correspond to about \$125 million in annual retail sales. She says Questcor has also provided a total of \$360 million worth of free Acthar through the National Organization for Rare Disorders. The company's never explained how it distributes all those free vials, which contain five doses and have a value of \$30,000 each.

When Questcor raised the price of a vial of Acthar from \$1,650 to \$23,000 in 2007, the drug was mainly used to treat infantile spasm, a rare kind of seizure afflicting babies, for which Acthar is a standard treatment.

Infantile syndrome is now a small part of Acthar's value to Questcor. The drug label has 18 other disease indications. Questcor's net sales more than doubled last year, topping \$500 million, while earnings grew 150%, to about \$200 million, or \$3.14 a share. At an investor conference last month, the company estimated that 10% of Acthar sales were for infantile spasm, 30% for multiple sclerosis, 40% for a kidney disease, and 18% for arthritis and related illnesses.

After the co-pay, a course of Acthar treatment for some of these ailments can cost insurers or the government hundreds of thousands of dollars.

Questcor doesn't disclose what portion of Acthar sales go to patients covered by commercial insurance or government programs like Medicaid, but in its financial statements it must reserve for the various price rebates the government is allowed. By analyzing these reserves, *Barron's* estimates that

before rebates) in the six months ended June 2013, up from about 40% in the corresponding year-earlier period.

There has also been a seemingly sharp recent rise in sales to patients covered by Medicaid and the military's Tricare. Tricare beneficiaries make up about 3% of Americans with health coverage, but Tricare sales seem to have risen this year to 5% of Questcor's total. Records of Tricare's Acthar claims, released pursuant to a Freedom of Information request, show the drug being prescribed by a South Carolina dentist and orthopedic surgeons (who didn't respond to our queries). The apparent jump in Acthar usage among the Medicaid population correlates with a reduction in the government's rebate that made Medicaid sales of Acthar profitable for the first time to Questcor.

It may become harder to boost Acthar sales through government channels. In a meeting last month, Tricare's medical advisory panel recommended that the program not cover Acthar for arthritis and to provide it for multiple sclerosis and kidney treatment only upon appeal.

Also in September, three of Medicare's 10 regional administrators excluded Acthar from coverage under the Medicare Part B program for outpatient medical services, because most patients administer the drug themselves. Yet Part B submissions totaled about a quarter of Medicare claims for Acthar, according to insurance-claims databases that *Barron's* reviewed.

Ever since Medicare added its Part D drug benefit, the program's guardians have worried about drug companies subsidizing a patient's co-payment to induce an expensive Medicare drug claim. In a 2005 advisory bulletin, the OIG warned co-pay charities against defining disease categories so narrowly that the earmarking effectively results in the subsidization of the donor's particular products. At the time that Questcor filings first mentioned the CDF, the charity already had a program for multiple sclerosis drugs. Still, the CDF launched a program for "acute exacerbations of multiple sclerosis"—language that echoes the label of Acthar, but not those of other drugs on the CDF's roster. CDF Executive Director Clorinda Walley in a Friday e-mail confirmed that the sole drug supplied under that co-pay program was Acthar.

"We follow the OIG guidelines," said the charity's outside counsel Tom Fox, of the Washington law firm Reed Smith. "There is no steering that takes place whatsoever."

E-mail: editors@barrons.com

If You Want a Quick Recovery, Forgive Debts BARRON'S

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EXHIBIT D

The New York Times

<https://nyti.ms/JCaFwF>

Drug Maker's Donations to Co-Pay Charity Face Scrutiny

By Andrew Pollack

Dec. 18, 2013

As drug prices have soared in recent years and insurers have increased co-payments, a new type of charity has blossomed to fill a vital niche — helping patients pay the steep out-of-pocket costs for their medicines.

But the largest of these co-payment assistance charities, the Chronic Disease Fund, is now in turmoil after questions have arisen about its relationship with a pharmaceutical company that is itself under investigation for its marketing practices.

The practice is casting light on what has long been an open secret: The bulk of the contributions to these charities come from the pharmaceutical companies. The foundations not only help hundreds of thousands of patients a year, they also raise drug company sales and profits.

After all, if a patient cannot afford out-of-pocket costs of \$5,000 for a \$100,000-a-year drug, the drug company gets nothing. But if the manufacturer or the charity pays the \$5,000, the patient gets the drug and the company receives \$95,000 from the patient's insurance company or Medicare.

The contributions — which also provide tax deductions to drug makers — are legal as long as a company does not require that the money it donates be used exclusively to pay for its own drugs.

But articles circulating in the investment world have suggested that the Chronic Disease Fund might be showing improper favoritism toward Questcor Pharmaceuticals, which sells an expensive drug for immune diseases. Moreover,

the articles noted that the charity was purchasing millions of dollars a year in services from for-profit companies owned by the charity's founder and president, Michael Banigan.

Questcor and the charity have said they are victims of a campaign by short-sellers — investors who benefit from the decline of a stock's price.

Nonetheless, fearing defections from donors, the charity hired a Washington law firm, Venable, to evaluate its practices and recommend changes to ensure it was in compliance with legal requirements.

As a result, Mr. Banigan is leaving the charity and the entire board has been replaced. The charity is also revamping policies in a way that could eliminate co-pay assistance for certain drugs, according to Jeffrey S. Tenenbaum, the head of the nonprofit organizations practice at Venable.

“When an organization comes under great scrutiny like C.D.F. has come under, you have to make sure they are squeaky clean,” Mr. Tenenbaum said in an interview. He said he thought the fund and Mr. Banigan had good intentions but “just didn’t know some of the things they should be doing.”



Michael Banigan, founder of the Chronic Disease Fund, is leaving the charity.

Mr. Tenenbaum said the charity was cooperating with a request for information in a federal investigation of Questcor's marketing practices. He also said that the fund itself was "absolutely not a target of that or any other investigation." Nonetheless, he said, he had advised the fund that an investigation might be coming.

He said the controversy "definitely has gotten the drug companies' attention." While no company has ended its donations, some were still considering what to do, he said.

The Chronic Disease Fund, which is based in Plano, Tex., received \$200 million in contributions in 2012, triple its 2007 total and ranking it among the 50 largest charities in the United States. It says it helped nearly 86,000 patients last year and more than 500,000 since its inception in 2003.

Critics say co-pay assistance helps keep drug prices high and circumvents efforts by insurers to control drug spending by making consumers bear part of the cost.

“These subsidies are unfortunately used to promote the overutilization of expensive brand-name drugs,” said Wells Wilkinson, a lawyer at Community Catalyst, a consumer advocacy organization.

The charities counter that any benefit to the drug companies is secondary to helping patients.

“Look at the alternative,” said Dana Kuhn, founder and president of Patient Services, one of the charities. “If they didn’t donate their dollars, people would die.”

Drug companies often directly subsidize the co-payments for privately insured patients. But they cannot do so for patients covered by federal programs like Medicare’s Part D drug benefit, because that would be considered a kickback, an illegal inducement to use a drug.

So the drug companies donate to the co-pay assistance charities. A handful of charities specialize in providing such help. In addition, some patient advocacy groups like the Leukemia and Lymphoma Society have similar programs.

Some executives of these charities now worry about increased scrutiny.

“We could all get painted with the same brush,” said Patrick McKercher, president of the Patient Access Network Foundation. Its contributions more than doubled in 2012 to \$179 million. It expects to help more than 100,000 patients this year, an increase from 59,000 in 2012.

The charities are supposed to solicit donations from the public, not just drug companies. Still, 81 percent of the contributions to the Chronic Disease Fund in 2011 came from two pharmaceutical companies, according to its financial report for the year. The companies were not identified.

Drug companies cannot contribute money specifically for their own drugs. Rather, they donate money to provide co-payment assistance for people with a specific disease, regardless of which drug is used. The Chronic Disease Fund, its website says, provides co-pay assistance for 78 drugs used to treat 46 diseases.

For 15 of those diseases there is only one drug available, however, meaning the manufacturer of that drug can be certain its contribution will be spent on co-pays for its product.

The articles raising questions about the fund were published in October in Barron's and on the investor website Seeking Alpha.

The latter was written by an anonymous short-seller of Questcor stock.

Questcor sells a drug called H.P. Acthar Gel, which was approved more than 60 years ago to treat a variety of immune-related conditions. The company, which acquired the drug in 2001, has raised its price since then from \$40 to more than \$28,000 a vial.

It has been gradually expanding the marketing of its drug to different diseases. And as it does so, it appears the Chronic Disease Fund has started co-pay assistance for those diseases.

For instance, although the fund already offered support for multiple sclerosis, it started a new program for "acute exacerbations of M.S.," which applies only to Acthar.

The fund does not provide co-pay assistance for an approved drug for lupus, but it does for "exacerbations of lupus," a use of Acthar.

Questcor's contributions for co-pay assistance are increasing even faster than sales of Acthar. Its contribution of \$9 million in the first nine months of this year was 74 percent higher than the same period a year earlier. Its total 2012 contribution of \$8 million was quadruple the level in 2011.

Don M. Bailey, Questcor's chief executive, said at an investor conference last week that the company was "doing exactly the same thing everybody else is doing" in contributing to the charity.

Mr. Tenenbaum, the lawyer, said the fund would no longer provide co-pay assistance for diseases treatable by only a single drug, unless there was clearly a second drug in development. And he said the fund would sever all ties with companies owned by Mr. Banigan, its departing president.

Mr. Banigan declined to comment. But in an email the fund forwarded to donors last week, he wrote: "There are many things I still want to accomplish in my lifetime and with C.D.F. well positioned for the future, I believe this is the right time for me to step aside and let others carry the organization forward."

Clorinda Walley, the executive director, will now run the organization. She issued a letter last week calling the earlier articles misleading but wrote that the charity was nonetheless making changes to its structure and practices aimed at "not just meeting, but exceeding best practices for nonprofit charities."

EXHIBIT E



U.S. FOOD & DRUG ADMINISTRATION

[FDA Home](#)³ [Developing Products for Rare Diseases & Conditions](#)⁴

Search Orphan Drug Designations and Approvals

Generic Name:	repository corticotropin or adrenocorticotrophic hormone
Trade Name:	H.P. Acthar Gel
Date Designated:	05/21/2003
Orphan Designation:	Treatment of infantile spasms
Orphan Designation Status:	Designated/Approved
Marketing Approval Date:	10/15/2010
Approved Labeled Indication:	To treat infantile spasms
Exclusivity End Date:	10/15/2017
Exclusivity Protected Indication*:	
Sponsor:	Questcor Pharmaceuticals, Inc. 26118 Research Road Hayward, California 94545 USA

The sponsor address listed is the last reported by the sponsor to OOPD.

*Exclusivity Protected Indications are shown for approvals from Jan. 1, 2013, to the present.

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U.S. Department of **Health & Human Services**

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Ex. 33

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EXHIBIT F

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022432Orig1s000

Trade Name: H.P. Acthar Gel

Generic Name: Repository Corticotropin Injection

Sponsor: Questcor Pharmaceuticals, Inc.

Approval Date: October 15, 2010

Indications: an adrenocorticotrophic hormone (ACTH) analogue indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age;

Indicated for the treatment of exacerbations of multiple sclerosis in adults;

May be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
022432Orig1s000

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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022432Orig1s000

APPROVAL LETTER



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022432

NDA APPROVAL

Questcor Pharmaceuticals, Inc.
Attention: Sian Bigora, Pharm.D.
Vice President, Regulatory Affairs
3260 Whipple Road
Union City, CA 94587

Dear Dr. Bigora:

Please refer to your New Drug Application (NDA) dated June 16, 2006, received June 23, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for H.P. Acthar[®] Gel (repository corticotropin) Injection.

We acknowledge receipt of your amendments dated December 10, 2009, and January 19, April 1, 22, and 28, June 8, and August 10, 2010.

The December 10, 2009, submission constituted a complete response to our May 10, 2007, action letter.

This new drug application provides for the use of H.P. Acthar[®] Gel (repository corticotropin) to treat infantile spasms.

We have completed our review of this application, as amended, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert and Medication Guide). Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

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<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the enclosed carton and immediate container labels, except with the revisions listed below, as soon as they are available, but no more than 30 days after they are printed.

1. Because H.P. Acthar Gel is a multiple-dose injectable product, the strength per total volume should be the primary and prominent expression on the principle display panel, followed in close proximity by the strength per mL enclosed by parenthesis per USP standards. Please revise the strength expression on all labels and labeling to read as follows:

400 USP units/5 mL
(80 USP units/mL)

2. Relocate the strength expression immediately following the established name presentation in all labels and labeling.

Please submit these labels electronically according to the guidance for industry titled “Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008).” Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission “**Final Printed Carton and Container Labels for approved NDA 022432.**” Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because this drug product for this indication has an orphan drug designation, you are exempt

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from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY REQUIREMENTS

Section 505-1 of the FDCA authorizes FDA to require the submission of a risk evaluation and mitigation strategy (REMS), if FDA determines that such a strategy is necessary to ensure that the benefits of the drug outweigh the risks [section 505-1(a)]. The details of the REMS requirements were outlined in our REMS notification letter dated September 27, 2010.

H.P. Acthar Gel (repository corticotrophin) was approved on April 29, 1952, for multiple indications. The label was later expanded to include multiple sclerosis (MS) in 1972. We are now adding the indication of infantile spasms in pediatric patients. The known risks of infections and blood pressure elevation in MS patients have also been identified as risks in the pediatric population based on clinical trial data. Additionally, the risk of adrenal insufficiency seen in other patient populations is an important potential serious adverse event in the pediatric population. The extension of the indication to pediatrics changes the risk benefit profile of H.P. Acthar Gel (repository corticotrophin) and is considered to be “new safety information” as defined in section 505-1(b)(3) of the FDCA.

Your proposed REMS, submitted on September 28, 2010, and appended to this letter, is approved. The REMS consists of a Medication Guide and timetable for submission of assessments of the REMS.

The REMS assessment plan should include, but is not limited to, the following:

An evaluation of patients’ understanding of the serious risks of H.P. Acthar[®] Gel (repository corticotropin).

Assessments of an approved REMS must also include, under section 505-1(g)(3)(B) and (C), information on the status of any postapproval study or clinical trial required under section 505(o) or otherwise undertaken to investigate a safety issue. With respect to any such postapproval study, you must include the status of such study, including whether any difficulties completing the study have been encountered. With respect to any such postapproval clinical trial, you must include the status of such clinical trial, including whether enrollment has begun, the number of participants enrolled, the expected completion date, whether any difficulties completing the clinical trial have been encountered, and registration information with respect to requirements under subsections (i) and (j) of section 402 of the Public Health Service Act. You can satisfy these requirements in your REMS assessments by referring to relevant information included in the most recent annual report required under section 506B and 21 CFR 314.81(b)(2)(vii) and including any material or significant updates to the status information since the annual report was prepared. Failure to comply with the REMS assessments provisions in section 505-1(g) could result in enforcement action.

We remind you that in addition to the assessments submitted according to the timetable included in the approved REMS, you must submit a REMS assessment and may propose a modification to the approved REMS when you submit a supplemental application for a new indication for use as described in section 505-1(g)(2)(A) of FDCA.

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If you currently distribute or plan to distribute an authorized generic product under this NDA, you will also need to submit a REMS, REMS supporting document, and any required appended documents for that authorized generic, to this NDA. In other words, you must submit a complete proposed REMS that relates only to the authorized generic product. Review and approval of the REMS is required before you may market your product.

Prominently identify the submission containing the REMS assessments or proposed modifications with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 008372 REMS ASSESSMENT

**NEW SUPPLEMENT FOR NDA 008372
PROPOSED REMS MODIFICATION
REMS ASSESSMENT**

**NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 008372
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)**

If you do not submit electronically, please send 5 copies of REMS-related submissions.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>.

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LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original **NDA 008372** for this drug product, not to this NDA. In the future, do not make submissions to this NDA except for the final printed labeling requested above.

If you have any questions, call Susan Daugherty, Regulatory Project Manager, at (301) 796-0878.

Sincerely,

{See appended electronic signature page}

Russell Katz, M.D.
Director
Division of Neurology Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

ENCLOSURES:

Content of Labeling
Carton and Container Labeling
REMS

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

RUSSELL G KATZ
10/15/2010

EXHIBIT G

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
022432Orig1s000

LABELING

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use H.P. Acthar Gel safely and effectively. See full prescribing information for H.P. Acthar Gel.

H.P. Acthar Gel (repository corticotropin) INJECTION, GEL for INTRAMUSCULAR | SUBCUTANEOUS use

Initial U.S. Approval: 1952

RECENT MAJOR CHANGES

- Indications and Usage, (1) 10/10
- Dosage and Administration, (2) 10/10
- Contraindications, Infantile Spasms (4) 10/10
- Warnings and Precautions (5) 10/10

INDICATIONS AND USAGE

- H.P. Acthar Gel is an adrenocorticotrophic hormone (ACTH) analogue indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age. (1.1)
- H.P. Acthar Gel is indicated for the treatment of exacerbations of multiple sclerosis in adults. (1.2)
- H.P. Acthar Gel may be used for the following disorders and diseases: rheumatic; collagen; dermatologic; allergic states; ophthalmic; respiratory; and edematous state; (1.3 to 1.9)

DOSAGE AND ADMINISTRATION

- In the treatment of infantile spasms, the recommended dose is 150 U/m² divided into twice daily intramuscular injections of 75 U/m². After 2 weeks of treatment, dosing should be gradually tapered and discontinued over a 2-week period. (2.1)
- In the treatment of acute exacerbations of multiple sclerosis, daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks may be administered. It may be necessary to taper the dose. (2.2)
- In the treatment of other disorders and diseases, dosing will need to be individualized depending on the disease under treatment and the medical condition of the patient. It may be necessary to taper the dose. (2.3)

DOSAGE FORMS AND STRENGTHS

- 5 mL multi-dose vial containing 80 USP units per mL (3)

CONTRAINDICATIONS

- H.P. Acthar Gel should never be given intravenously.
- H.P. Acthar Gel is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, or sensitivity to proteins of porcine origin.
- Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of H.P. Acthar Gel.
- H.P. Acthar Gel is contraindicated in children under 2 years of age with suspected congenital infections. (4)
- Treatment of conditions listed within the INDICATIONS section is contraindicated when they are accompanied by primary adrenocortical insufficiency or adrenocortical hyperfunction. (4)

WARNINGS AND PRECAUTIONS

- Infections: Increased susceptibility to new infection and increased risk of exacerbation, dissemination or reactivation of latent infections. Signs and symptoms of infection may be masked. (5.1)
- Adrenal Insufficiency after Prolonged Therapy: Monitor for effects of

- hypothalamic-pituitary-axis suppression after stopping treatment. (5.2)
- Cushing's Syndrome: May occur after prolonged therapy. Monitor for signs and symptoms. (5.2)
- Elevated Blood Pressure, Salt and Water Retention and Hypokalemia: Monitor blood pressure and sodium and potassium levels. (5.3)
- Vaccination: Do not administer live or attenuated vaccines to patients on immunosuppressive doses. (5.4)
- Masking of Symptoms of Other Underlying Disease/Disorders. Monitor patients for signs of other underlying disease/disorders that may be masked. (5.5)
- Gastrointestinal Perforation and Bleeding: There is a risk for gastric ulcers and bleeding. There is an increased risk of perforation in patients with certain GI disorders. Signs and symptoms may be masked. Monitor for signs of perforation and bleeding. (5.6)
- Behavioral and Mood Disturbances: May include euphoria, insomnia, mood swings, personality changes, severe depression and psychosis. Existing conditions may be aggravated (5.7)
- Comorbid Diseases: Symptoms of diabetes and myasthenia gravis may be worsened with treatment. (5.8)
- Ophthalmic Effects: Monitor for cataracts, infections and glaucoma. (5.9)
- Immunogenicity Potential: Neutralizing antibodies with chronic administration may lead to a loss of endogenous ACTH activity. (5.10)
- Use in Patients with Hypothyroidism or Liver Cirrhosis: May result in an enhanced effect. (5.11)
- Negative Effects on Growth and Physical Development: Monitor pediatric patients on long term therapy. (5.12)
- Decrease in Bone Density: Monitor for osteoporosis in patients on long term therapy. (5.13)
- Use in Pregnancy: Embryocidal effect. Apprise women of potential harm to the fetus. (5.14)

ADVERSE REACTIONS

- Common adverse reactions for Acthar Gel are similar to those of corticosteroids and include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain. (6)
- Specific adverse reactions resulting from drug use in children under 2 years of age are increased risk of infections, hypertension, irritability, Cushingoid symptoms, cardiac hypertrophy and weight gain. (6.1.1)

To report SUSPECTED ADVERSE REACTIONS, contact Questcor Pharmaceuticals, Inc. at (800) 411-3065 or (510) 400-0700 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch

DRUG INTERACTIONS

- H.P. Acthar Gel may accentuate the electrolyte loss associated with diuretic therapy. (7)

USE IN SPECIFIC POPULATIONS

- Pregnancy: H.P. Acthar Gel has been shown to have an embryocidal effect and should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (8.1) Pediatric Use: Prolonged use of H.P. Acthar Gel in children may inhibit skeletal growth. If use is necessary, it should be given intermittently with careful observation. (5.12 and 8.3)

See 17 for Patient Counseling Information and FDA-approved Medication Guide

FULL PRESCRIBING INFORMATION: CONTENTS***FULL PRESCRIBING INFORMATION****1 INDICATIONS AND USAGE**

- 1.1 Infantile spasms;
- 1.2 Multiple Sclerosis;
- 1.3 Rheumatic Disorders;
- 1.4 Collagen Diseases;
- 1.5 Dermatologic Diseases;
- 1.6 Allergic States;
- 1.7 Ophthalmic Diseases;
- 1.8 Respiratory Diseases;
- 1.9 Edematous State;

2 DOSAGE AND ADMINISTRATION

- 2.1 Specific Recommended Dosage Regimen for Infantile Spasms in Infants and Children Under 2 Years of Age
- 2.2 Recommended Dosage Regimen for the Treatment of Acute Exacerbations in Adults with Multiple Sclerosis.
- 2.3 Recommended Dosage Regimen for Other Indications for Adults and Children Over 2 Years of Age
- 2.4 Preparation

3 DOSAGE FORMS AND STRENGTHS**4 CONTRAINDICATIONS****5 WARNINGS AND PRECAUTIONS**

- 5.1 Infections
- 5.2 Cushing's Syndrome and Adrenal Insufficiency Upon Withdrawal

5.3	Elevated Blood Pressure, Salt and Water Retention and Hypokalemia
5.4	Vaccination
5.5	Masking Symptoms of Other Diseases
5.6	Gastrointestinal Perforation and Bleeding
5.7	Behavioral and Mood Disturbances
5.8	Comorbid Diseases
5.9	Ophthalmic Effects
5.10	Immunogenicity Potential
5.11	Use in Patients with Hypothyroidism or Liver Cirrhosis
5.12	Negative Effects on Growth and Physical Development
5.13	Decrease in Bone Density
5.14	Use in Pregnancy
6	ADVERSE REACTIONS
6.1	Clinical Studies Experience
6.1.1	Adverse Reactions in Infants and Children Under 2 Years of Age
6.2	Postmarketing Experience
6.2.1	Allergic Reactions
6.2.2	Cardiovascular
6.2.3	Dermatologic
6.2.4	Endocrine
6.2.5	Gastrointestinal
6.2.6	Metabolic

*Sections or subsections omitted from the full prescribing information are not listed

6.2.7	Musculoskeletal
6.2.8	Neurological
6.3	Possible Additional Steroidogenic Effects
6.3.1	Dermatologic
6.3.2	Endocrine
6.3.3	Metabolic
6.3.4	Musculoskeletal
6.3.5	Neurological
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7	DRUG INTERACTIONS
8	USE IN SPECIFIC POPULATIONS
8.1	Pregnancy
8.3	Nursing Mothers
8.4	Pediatric Use
10	OVERDOSAGE
11	DESCRIPTION
12	CLINICAL PHARMACOLOGY
12.1	Mechanism of Action
13	NONCLINICAL TOXICOLOGY
13.1	Carcinogenesis, Mutagenesis, Impairment of Fertility
14	CLINICAL STUDIES
16	HOW SUPPLIED / STORAGE AND HANDLING
17	PATIENT COUNSELING INFORMATION

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Infantile spasms:

H.P. Acthar Gel (repository corticotropin injection) is indicated as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age.

1.2 Multiple Sclerosis:

H.P. Acthar Gel (repository corticotropin injection) is indicated for the treatment of acute exacerbations of multiple sclerosis in adults. Controlled clinical trials have shown H.P. Acthar Gel to be effective in speeding the resolution of acute exacerbations of multiple sclerosis. However, there is no evidence that it affects the ultimate outcome or natural history of the disease.

1.3 Rheumatic Disorders:

As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis, Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy), Ankylosing spondylitis.

1.4 Collagen Diseases:

During an exacerbation or as maintenance therapy in selected cases of: systemic lupus erythematosus, systemic dermatomyositis (polymyositis).

1.5 Dermatologic Diseases:

Severe erythema multiforme, Stevens-Johnson syndrome.

1.6 Allergic States:

Serum sickness.

1.7 Ophthalmic Diseases:

Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: keratitis, iritis, iridocyclitis, diffuse posterior uveitis and choroiditis; optic neuritis; chorioretinitis; anterior segment inflammation.

1.8 Respiratory Diseases:

Symptomatic sarcoidosis

1.9 Edematous State:

To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

2 DOSAGE AND ADMINISTRATION**2.1 Specific Recommended Dosage Regimen for Infantile Spasms in Infants and Children Under 2 Years of Age**

In the treatment of infantile spasms, H.P. Acthar Gel must be administered intramuscularly. The recommended regimen is a daily dose of 150 U/m² (divided into twice daily intramuscular injections of 75 U/m²) administered over a 2-week period. Dosing with H.P. Acthar Gel should then be gradually tapered over a 2-week period to avoid adrenal insufficiency. The following is one suggested tapering schedule: 30 U/m² in the morning for 3 days; 15 U/m² in the morning for 3 days; 10 U/m² in the morning for 3 days; and 10 U/m² every other morning for 6-days.

H.P. Acthar Gel is typically dosed based on body surface area (BSA). For calculation of body surface area, use the following formula

$$BSA(m^2) = \sqrt{\frac{weight \text{ (kg)} \times height \text{ (cm)}}{3600}}$$

2.2 Recommended Dosage Regimen for the Treatment of Acute Exacerbations in Adults with Multiple Sclerosis.

The recommended dose is daily intramuscular or subcutaneous doses of 80-120 units for 2-3 weeks for acute exacerbations.

Dosage should be individualized according to the medical condition of each patient. Frequency and dose of the drug should be determined by considering the severity of the disease and the initial response of the patient.

Although drug dependence does not occur, sudden withdrawal of H.P. Acthar Gel after prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

2.3 Recommended Dosage Regimen for Other Indications for Adults and Children Over 2 Years of Age

Dosage should be individualized according to the disease under treatment and the general medical condition of each patient. Frequency and dose of the drug should be determined by considering severity of the disease and the initial response of the patient.

The usual dose of H.P. Acthar Gel is 40-80 units given intramuscularly or subcutaneously every 24-72 hours.

Although drug dependence does not occur, sudden withdrawal of H.P. Acthar Gel after prolonged use may lead to adrenal insufficiency or recurrent symptoms which make it difficult to stop the treatment. It may be necessary to taper the dose and increase the injection interval to gradually discontinue the medication.

2.4 Preparation

H.P. Acthar Gel should be warmed to room temperature before using.

Caution should be taken not to over-pressurize the vial prior to withdrawing the product.

3 DOSAGE FORMS AND STRENGTHS

5 mL multi-dose vial containing 80 USP Units per mL.

4 CONTRAINDICATIONS

H.P. Acthar Gel is contraindicated for intravenous administration.

H.P. Acthar Gel is contraindicated where congenital infections are suspected in infants.

Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of H.P. Acthar Gel.

H.P. Acthar Gel is contraindicated in patients with scleroderma, osteoporosis, systemic fungal infections, ocular herpes simplex, recent surgery, history of or the presence of a peptic ulcer, congestive heart failure, uncontrolled hypertension, primary adrenocortical insufficiency, adrenocortical hyperfunction or sensitivity to proteins of porcine origin.

5 WARNINGS AND PRECAUTIONS

The adverse effects of H.P. Acthar Gel are related primarily to its steroidogenic effects. Not all of the adverse events described below have been seen after treatment with H.P. Acthar Gel, but might be expected to occur. [*see Adverse Reactions (6.3)*].

5.1 Infections

H.P. Acthar Gel may increase the risks related to infections with any pathogen, including viral, bacterial fungal, protozoan or helminthic infections. Patients with latent tuberculosis or tuberculin reactivity should be observed closely, and if therapy is prolonged, chemoprophylaxis should be instituted.

5.2 Cushing's Syndrome and Adrenal Insufficiency Upon Withdrawal

Treatment with H.P. Acthar Gel can cause hypothalamic-pituitary-axis (HPA) suppression and Cushing's syndrome. These conditions should be monitored especially with chronic use.

Suppression of the HPA may occur following prolonged therapy with the potential for adrenal insufficiency after withdrawal of the medication. Patients should be monitored for signs of insufficiency such as weakness, hyperpigmentation, weight loss, hypotension and abdominal pain.

The symptoms of adrenal insufficiency in infants treated for infantile spasms can be difficult to identify. The symptoms are non-specific and may include anorexia, fatigue, lethargy, weakness, excessive weight loss, hypotension and abdominal pain. It is critical that parents and caregivers be made aware of the possibility of adrenal insufficiency when discontinuing Acthar Gel and should be instructed to observe for, and be able to recognize, these symptoms [*see Information for Patients (17)*]

The recovery of the adrenal gland may take from days to months so patients should be protected from the stress (e.g. trauma or surgery) by the use of corticosteroids during the period of stress.

The adrenal insufficiency may be minimized in adults and infants by tapering of the dose when discontinuing treatment.

Signs or symptoms of Cushing's syndrome may occur during therapy but generally resolve after therapy is stopped. Patients should be monitored for these signs and symptoms such as deposition of adipose tissue in characteristic sites (e.g., moon face, truncal obesity), cutaneous striae, easy bruisability, decreased bone mineralization, weight gain, muscle weakness, hyperglycemia, and hypertension.

5.3 Elevated Blood Pressure, Salt and Water Retention and Hypokalemia

H.P. Acthar Gel can cause elevation of blood pressure, salt and water retention, and increased excretion of potassium and calcium. Dietary salt restriction and potassium supplementation may

be necessary. Caution should be used in the treatment of patients with hypertension, congestive heart failure, or renal insufficiency.

5.4 Vaccination

Administration of live or live attenuated vaccines is contraindicated in patients receiving immunosuppressive doses of H.P. Acthar Gel. Killed or inactivated vaccines may be administered; however, the response to such vaccines can not be predicted. Other immunization procedures should be undertaken with caution in patients who are receiving H.P. Acthar Gel, especially when high doses are administered, because of the possible hazards of neurological complications and lack of antibody response.

5.5 Masking Symptoms of Other Diseases

H.P. Acthar Gel often acts by masking symptoms of other diseases/disorders without altering the course of the other disease/disorder. Patients should be monitored carefully during and for a period following discontinuation of therapy for signs of infection, abnormal cardiac function, hypertension, hyperglycemia, change in body weight and fecal blood loss.

5.6 Gastrointestinal Perforation and Bleeding

Acthar Gel can cause GI bleeding and gastric ulcer. There is also an increased risk for perforation in patients with certain gastrointestinal disorders. Signs of gastrointestinal perforation, such as peritoneal irritation, may be masked by the therapy. Use caution where there is the possibility of impending perforation, abscess or other pyogenic infections, diverticulitis, fresh intestinal anastomoses, and active or latent peptic ulcer.

5.7 Behavioral and Mood Disturbances

Use of H.P. Acthar Gel may be associated with central nervous system effects ranging from euphoria, insomnia, irritability (especially in infants), mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated.

5.8 Comorbid Diseases

Patients with a comorbid disease may have that disease worsened. Caution should be used when prescribing H.P. Acthar Gel in patients with diabetes and myasthenia gravis.

5.9 Ophthalmic Effects

Prolonged use of H.P. Acthar Gel may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves and may enhance the establishment of secondary ocular infections due to fungi and viruses.

5.10 Immunogenicity Potential

H.P. Acthar Gel is immunogenic. Limited available data suggest that a patient may develop antibodies to H.P. Acthar Gel after chronic administration and loss of endogenous ACTH and H.P. Acthar Gel activity. Prolonged administration of H.P. Acthar Gel may increase the risk of hypersensitivity reactions. Sensitivity to porcine protein should be considered before starting therapy and during the course of treatment should symptoms arise.

5.11 Use in Patients with Hypothyroidism or Liver Cirrhosis

There is an enhanced effect in patients with hypothyroidism and in those with cirrhosis of the liver.

5.12 Negative Effects on Growth and Physical Development

Long-term use of H.P. Acthar Gel may have negative effects on growth and physical development in children. Changes in appetite are seen with H.P. Acthar Gel therapy, with the effects becoming more frequent as the dose or treatment period increases. These effects are reversible once H.P. Acthar Gel therapy is stopped. Growth and physical development of pediatric patients on prolonged therapy should be carefully monitored.

5.13 Decrease in Bone Density

Decrease in bone formation and an increase in bone resorption both through an effect on calcium regulation (i.e. decreasing absorption and increasing excretion) and inhibition of osteoblast function may occur. These, together with a decrease in the protein matrix of the bone (secondary to an increase in protein catabolism) and reduced sex hormone production, may lead to inhibition of bone growth in children and adolescents and to the development of osteoporosis at any age. Special consideration should be given to patients at increased risk of osteoporosis (i.e., postmenopausal women) before initiating therapy, and bone density should be monitored in patients on long term therapy.

5.14 Use in Pregnancy

H.P. Acthar Gel has been shown to have an embryocidal effect. Apprise women of potential harm to the fetus. [*see Use in Specific Populations (8.1)*]

6 ADVERSE REACTIONS

Please refer to *Adverse Reactions in Infants and Children Under 2 Years of Age (Section 6.1.1)* for consideration when treating patients with Infantile Spasms. The adverse reactions presented in Section 6.2 are primarily provided for consideration in use in adults and in children over 2 years of age, but these adverse reactions should also be considered when treating infants and children under 2 years of age.

H.P. Acthar Gel causes the release of endogenous cortisol from the adrenal gland. Therefore all the adverse effects known to occur with elevated cortisol may occur with H.P. Acthar Gel administration as well. Common adverse reactions include fluid retention, alteration in glucose tolerance, elevation in blood pressure, behavioral and mood changes, increased appetite and weight gain.

6.1 Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug, and may not reflect the rates observed in practice.

6.1.1 Adverse Reactions in Infants and Children Under 2 Years of Age

While the types of adverse reactions seen in infants and children under age 2 treated for infantile spasms are similar to those seen in older patients, their frequency and severity may be different due to the very young age of the infant, the underlying disorder, the duration of therapy and the dosage regimen. Below is a summary of adverse reactions specifically tabulated from source data derived from retrospective chart reviews and clinical trials in children under 2 years of age treated for infantile spasms. The number of patients in controlled trials at the recommended dose was too few to provide meaningful incidence rates or to permit a meaningful comparison to the control groups.

TABLE: Incidence (%) of Treatment Emergent Adverse Events Occurring in $\geq 2\%$ of H.P. Acthar Gel (repository corticotropin injection) Infants and Children under 2 years of Age

System Organ Class	Recommended 75 U/m ² bid n=122, (%)	150 U/m ² qd n=37 (%)
Cardiac disorders		
Cardiac Hypertrophy	3	0
Endocrine disorders		
Cushingoid	3	22
Gastrointestinal disorders		
Constipation	0	5
Diarrhea	3	14
Vomiting	3	5
General disorders and administration site conditions		
Irritability	7	19
Pyrexia	5	8
Infections and infestations		
Infection ¹	20	46

System Organ Class	Recommended 75 U/m² bid n=122, (%)	150 U/m² qd n=37 (%)
Investigations		
Weight gain	1	3
Metabolism and nutrition disorders		
Increased appetite	0	5
Decreased appetite	3	3
Nervous system disorders		
Convulsion ²	12	3
Respiratory, thoracic and mediastinal disorders		
Nasal Congestion	1	5
Skin and subcutaneous tissue disorders		
Acne	0	14
Rash	0	8
Vascular disorders		
Hypertension	11	19

¹ Specific infections that occurred at $\geq 2\%$ were candidiasis, otitis media, pneumonia and upper respiratory tract infections.² In the treatment of Infantile Spasms, other types of seizures/convulsions may occur because some patients with infantile spasms progress to other forms of seizures (for example, Lennox-Gastaut Syndrome). Additionally the spasms sometimes mask other seizures and once the spasms resolve after treatment, the other seizures may become visible.

These adverse reactions may also be seen in adults and children over 2 years of age when treated for other purposes and with different doses and regimens.

6.2 Postmarketing Experience

The following adverse reactions associated with the use of H.P. Acthar Gel have been identified from postmarketing experience with H.P. Acthar Gel. Only adverse events that are not listed above as adverse events reported from retrospective chart reviews and non-sponsor conducted clinical trials and those not discussed elsewhere in labeling, are listed in this section. Because the adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate their frequency or establish a causal relationship to use with H.P. Acthar Gel. Events are categorized by system organ class. Unless otherwise noted these adverse events have been reported in infants, children and adults.

6.2.1 Allergic Reactions

Allergic responses have presented as dizziness, nausea and shock (adults only).

6.2.2 Cardiovascular

Necrotizing angitis (adults only) and congestive heart failure.

6.2.3 Dermatologic

Skin thinning (adults only), facial erythema and increased sweating (adults only).

6.2.4 Endocrine

Decreased carbohydrate tolerance (infants only) and hirsutism.

6.2.5 Gastrointestinal

Pancreatitis (adults only), abdominal distention and ulcerative esophagitis.

6.2.6 Metabolic

Hypokalemic alkalosis (infants only).

6.2.7 Musculoskeletal

Muscle weakness and vertebral compression fractures (infants only).

6.2.8 Neurological

Headache (adults only), vertigo (adults only), subdural hematoma, intracranial hemorrhage (adults only), and reversible brain shrinkage (usually secondary to hypertension) (infants only).

6.3 Possible Additional Steroidogenic Effects

Based on steroidogenic effects of H.P. Acthar Gel certain adverse events may be expected due to the pharmacological effects of corticosteroids. The adverse events that may occur but have not been reported for H.P. Acthar Gel are:

6.3.1 Dermatologic

Impaired wound healing, abscess, petechiae and ecchymoses, and suppression of skin test reactions.

6.3.2 Endocrine

Menstrual irregularities.

6.3.3 Metabolic

Negative nitrogen balance due to protein catabolism.

6.3.4 Musculoskeletal

Loss of muscle mass and aseptic necrosis of femoral and humeral heads.

6.3.5 Neurological

Increased intracranial pressure with papilledema, (pseudo-tumor cerebri) usually after treatment, and subdural effusion.

6.3.6 Ophthalmic

Exophthalmos.

7 DRUG INTERACTIONS

Formal drug-drug interaction studies have not been performed.

H.P. Acthar Gel may accentuate the electrolyte loss associated with diuretic therapy.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Class C: H.P. Acthar Gel has been shown to have an embryocidal effect. There are no adequate and well-controlled studies in pregnant women. H.P. Acthar Gel should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

8.3 Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from H.P. Acthar Gel, when treating a nursing mother, a decision should be made whether to discontinue nursing or to discontinue the drug, considering the risk and benefit to the mother.

8.4 Pediatric Use

H.P. Acthar Gel is indicated as monotherapy for the treatment of infantile spasms in infants and children less than 2 years of age. Both serious and other adverse reactions in this population are discussed in Warnings and Adverse Reactions in Infants and Children Under 2 Years of Age [see Sections 5 and 6.1.1].

The efficacy of H.P. Acthar Gel for the treatment of infantile spasms in infants and children less than 2 years of age was evaluated in a randomized, single blinded (video EEG interpreter

blinded) clinical trial and an additional active control supportive trial [see *Clinical Studies (14)*]. A responding patient was defined as having both complete cessation of spasms and elimination of hypsarrhythmia.

Safety in the pediatric population for infantile spasms was evaluated by retrospective chart reviews and data from non-sponsor conducted clinical trials [see *Adverse Reactions (6.1.1)*]. While the types of adverse reactions seen in infants and children under 2 years of age treated for infantile spasms are similar to those seen in older patients, their frequency and severity may be different due to the very young age of the infant, the underlying disorder, the duration of therapy and the dosage regimen. Effects on growth are of particular concern [see *Warnings and Precautions (5.12)*]. Serious adverse reactions observed in adults may also occur in children [see *Warnings and Precautions (5)*].

10 OVERDOSAGE

While chronic exposure to H.P. Acthar Gel at high doses can be associated with a variety of potential serious adverse effects, it is not expected that a single high dose, or even several large doses, has the potential for serious adverse effects compared to a standard dose. There have been no reports of death or acute overdose symptoms from H.P. Acthar Gel in clinical studies or in the published literature.

The intramuscular route of administration makes it unlikely that an inadvertent acute overdose will occur. The typical daily dose of H.P. Acthar Gel to treat an infant that has a BSA of 0.4 m² would be 60 U/day. Using the 1-cc syringe supplied with H.P. Acthar Gel, the maximum amount that can be injected is 80 U/injection, which is a well-tolerated single dose.

11 DESCRIPTION

H.P. Acthar Gel is a highly purified sterile preparation of the adrenocorticotrophic hormone in 16% gelatin to provide a prolonged release after intramuscular or subcutaneous injection. Also contains 0.5% phenol, not more than 0.1% cysteine (added), sodium hydroxide and/or acetic acid to adjust pH and water for injection.

ACTH is a 39 amino acid peptide with the following chemical formula:

H-	Ser-	Tyr-	Ser-	Met-	Glu-	His-	Phe-	Arg-	Trp-	Gly-
	1	2	3	4	5	6	7	8	9	10
	Lys-	Pro-	Val-	Gly-	Lys-	Lys-	Arg-	Arg-	Pro-	Val-
	11	12	13	14	15	16	17	18	19	20
	Lys-	Val-	Try-	Pro-	Asp-	Gly-	Ala-	Glu-	Asp-	Gln-
	21	22	23	24	25	26	27	28	29	30
	Leu-	Ala-	Glu-	Ala-	Phe-	Pro-	Leu-	Glu-	Phe-	OH
	31	32	33	34	35	36	37	38	39	

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The mechanism of action of H.P. Acthar Gel in the treatment of infantile spasms is unknown.

H.P. Acthar Gel and endogenous ACTH stimulate the adrenal cortex to secrete cortisol, corticosterone, aldosterone, and a number of weakly androgenic substances. Prolonged administration of large doses of H.P. Acthar Gel induces hyperplasia and hypertrophy of the adrenal cortex and continuous high output of cortisol, corticosterone and weak androgens. The release of endogenous ACTH is under the influence of the nervous system via the regulatory hormone released from the hypothalamus and by a negative corticosteroid feedback mechanism. Elevated plasma cortisol suppresses ACTH release.

H.P. Acthar Gel is also reported to bind to melanocortin receptors.

The trophic effects of endogenous ACTH and H.P. Acthar Gel on the adrenal cortex are not well understood beyond the fact that they appear to be mediated by cyclic AMP.

ACTH rapidly disappears from the circulation following its intravenous administration; in people, the plasma half-life is about 15 minutes. The pharmacokinetics of H.P. Acthar Gel have not been adequately characterized.

The maximal effects of a trophic hormone on a target organ are achieved when optimal amounts of hormone are acting continuously. Thus, a fixed dose of H.P. Acthar Gel will demonstrate a linear increase in adrenocortical secretion with increasing duration for the infusion.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Adequate and well-controlled studies have not been done in animals. Human use has not been associated with an increase in malignant disease. [*see Warnings and Precautions (5.14) and Use in Specific Populations (8.1)*].

14 CLINICAL STUDIES

The effectiveness of H.P. Acthar Gel as a treatment for infantile spasms was demonstrated in a single blinded (video EEG interpreter blinded) clinical trial in which patients were randomized to receive either a 2 week course of treatment with H.P. Acthar Gel (75 U/m² intramuscular twice daily) or prednisone (1 mg/kg by mouth twice daily). The primary outcome was a comparison of the number of patients in each group who were treatment responders, defined as a patient having complete suppression of both clinical spasms and hypsarrhythmia on a full sleep cycle video EEG performed 2 weeks following treatment initiation, rated by an investigator blinded to treatment. Thirteen of 15 patients (86.7%) responded to Acthar Gel as compared to 4 of 14

patients (28.6%) given prednisone ($p < 0.002$). The 2-week treatment was followed by a 2-week period of taper. Nonresponders to the prednisone treatment were eligible to receive H.P. Acthar Gel treatment. Seven of 8 patients (87.5%) responded to H.P. Acthar Gel after not responding to prednisone. Similarly, the 2 nonresponder patients from the H.P. Acthar Gel treatment were eligible to receive treatment with prednisone. One of the 2 patients (50%) responded to the prednisone treatment after not responding to Acthar.

A supportive single-blind, randomized clinical trial comparing high-dose, long-duration treatment (150 U/m² once daily for 3 weeks, $n=30$) of H.P. Acthar Gel with low-dose, short-duration treatment (20 U once daily for 2 weeks, $n=29$) for the treatment of infantile spasms was also evaluated in infants and children less than 2 years of age. Nonresponders (defined as in the previously described study) in the low-dose group received a dose escalation at 2 weeks to 30 U once daily. Nominal statistical superiority of the high dose treatment, as compared to the low dose treatment, was observed for cessation of spasms but not for the resolution of hypsarrhythmia.

16 HOW SUPPLIED / STORAGE AND HANDLING

H.P. Acthar Gel (repository corticotropin injection) is supplied as 5 mL multi-dose vial (63004-7731-1) containing 80 USP Units per mL. H.P. Acthar Gel (repository corticotropin injection) should be warmed to room temperature before using. Do not over pressurize the vial prior to withdrawing the product.

Store H.P. Acthar Gel (repository corticotropin injection) under refrigeration between 2°-8°C (36°-46°F). Product is stable for the period indicated on the label when stored under the conditions described.

17 PATIENT COUNSELING INFORMATION

Caretakers of patients with infantile spasms should be informed of the availability of a Medication Guide, and they should be instructed to read the Medication Guide prior to administering H.P. Acthar Gel. Patients should be instructed to take H.P. Acthar Gel only as prescribed. They should not stop treatment suddenly unless instructed by their physician to do so.

Patients, their caregivers and families should be advised as to the importance of the need for careful monitoring while on and during titration from H.P. Acthar Gel treatment and the importance of not missing and scheduled doctor's appointments.

Patients, their caregivers and families should be advised that if the patient develops an infection or fever they should contact their physician. They should be educated that a fever may not necessarily be present during infection. The patient should also try to limit contact with other people with infections to minimize the risk of infection while taking H.P. Acthar Gel. [*see Warnings and Precautions (5.1) and Adverse Reactions (6.1.1)*]

Patients, their caregivers and families should be advised that if the patient experiences an increase in blood pressure they should contact their physician. [*see Warnings and Precautions (5.3) and Adverse Reactions (6.1.1)*]

Patients, their caregivers and families should be advised that if the patient or the caregiver notices blood or a change in color of the patient's stool they should contact their physician. [*see Warnings and Precautions (5.6)*].

Caregivers and families of infants and children treated with H.P. Acthar Gel should be informed that the patient may show signs of irritability and sleep disturbances. These effects are reversible once H.P. Acthar Gel therapy is stopped. [*see Warnings and Precautions (5.7) and Adverse Reactions (6.1.1)*].

Patients, their caregivers and families should be advised that changes in appetite, most often leading to weight gain, are seen with H.P. Acthar Gel therapy, becoming more frequent as the dose or treatment period increases. These effects are reversible once H.P. Acthar Gel therapy is stopped. [*see Warnings and Precautions (5.12) and Adverse Reactions (6.1.1)*].

Patients, their caregivers and families should be advised that the patient may be monitored for signs of adrenal insufficiency such as weakness, fatigue, lethargy, anorexia, weight loss, hypotension, abdominal pain or hyperpigmentation (adults only) after treatment has stopped. Since the recovery of the adrenal gland varies from days to months, patients may need to be protected from the stress of trauma or surgery by the use of corticosteroids during the period of stress. [*see Warnings and Precautions (5.2)*].

Patients should be advised not to be vaccinated with live or live attenuated vaccines during treatment with H.P. Acthar Gel. Additionally, other immunization procedures in patients or in family members who will be in contact with the patient should be undertaken with caution while the patient is taking H.P. Acthar Gel. [*see Warnings and Precautions (5.4)*].

Patients, their caregivers and families should be advised that prolonged use of H.P. Acthar Gel in children may result in Cushing's syndrome and associated adverse reactions, may inhibit skeletal growth, and may cause osteoporosis and decreased bone density. If prolonged use is necessary, H.P. Acthar Gel should be given intermittently along with careful observation. [*see Warnings and Precautions (5.2), (5.12), and (5.13) and Adverse Reactions (6.1.1)*].

Patients, their caregivers and families should be informed that H.P. Acthar may mask symptoms of other diseases/disorders without altering the course of the other disease/disorder. The patient will need to be monitored carefully during and for a period following discontinuation of therapy for signs of infection, abnormal cardiac function, hypertension, hyperglycemia, change in body weight, and fecal blood loss. [*see Warnings and Precautions (5.5)*].

In the treatment of Infantile Spasms, other types of seizures may occur because some patients with infantile spasms progress to other forms of seizures (for example, Lennox-Gastaut Syndrome). Additionally the spasms sometimes mask other seizures and once the spasms resolve after treatment with H.P. Acthar gel, the other seizures may become visible. Parents and caregivers should inform their physician of any new onset of seizures so that appropriate management can then be instituted. [*see Adverse Reactions (6.1.1)*].

H.P. Acthar[®] Gel
(repository corticotropin injection)

Manufactured for Questcor Pharmaceuticals, Inc.



QUESTCOR[®]

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MEDICATION GUIDE

H.P. Acthar® Gel (H P AK-thar jel) (repository corticotropin) Injection

This Medication Guide provides information only about the use of H.P. Acthar Gel for the treatment of Infantile Spasms. If your doctor prescribes H.P. Acthar Gel for you or your child for any other reason, talk to your doctor for information about how this medicine is used to treat your medical condition.

Read this Medication Guide before your child receives H.P. Acthar Gel and each time you refill your child's prescription. There may be new information. This Medication Guide does not take the place of talking with your doctor about your child's medical condition or treatment.

What is the most important information I should know about H.P. ACTHAR GEL?

H.P. Acthar Gel can cause serious side effects including:

- 1. Increased risk of infections.** H.P. Acthar Gel is a medicine that can affect your child's immune system. When your child is taking H.P. Acthar Gel, it can lower the ability of your child's immune system to fight infections. H.P. Acthar Gel may:
 - make your child more likely to get new infections
 - worsen an infection that your child already has
 - cause an inactive infection to become active, such as tuberculosis (TB)

Before starting H.P. Acthar Gel, tell your doctor if your child has:

- an infection or signs of an infection, such as:
 - fever
 - cough
 - vomiting
 - diarrhea
 - other signs of illness or flu
- a family member with an infection or signs of an infection

While taking H.P. Acthar Gel, your child should:

- stay away from people who are sick or who have infections
- tell your doctor right away if your child has any sign of infection such as:
 - fever (but your child may not have a fever with an infection)
 - cough
 - vomiting
 - diarrhea or

- other signs of illness or flu and
- any open cuts or sores on his or her body

2. Effects on the adrenal gland after stopping H.P. Acthar Gel.

When your child stops taking H.P. Acthar Gel, his or her body may not produce enough of a hormone called cortisol on its own (adrenal insufficiency). Your child may need to take steroid medicine to protect the body until the adrenal gland recovers and is working well again, especially to protect the body if they have surgery or trauma. **Do not stop giving your child injections of H.P. Acthar Gel without talking to your doctor first.** Your doctor will tell you when and how to slowly stop giving the injections to avoid serious side effects.

While slowly stopping your child's injections of H.P. Acthar Gel or after you stop giving the injections, call your doctor right away if your child has any of the following:

- appears weak
- loses weight or has a decrease in appetite
- appears tired or lacking energy
- appears pale
- has stomach pain
- appears sick or is with a fever

3. Effects on the adrenal gland while taking H.P. Acthar Gel

When your child is taking H.P. Acthar Gel, his or her adrenal gland may produce too much cortisol. This can cause symptoms of Cushing's syndrome. Cushing's syndrome is more common in children who take H.P. Acthar Gel for a long time.

Symptoms of Cushing's syndrome include:

- increased upper body fat around the neck, but not the arms and legs
- weight gain
- rounded or "moon" face
- thin skin, easy bruising, and stretch marks on thighs, belly and trunk
- slowed growth rates in children
- weak bones (osteoporosis)

While receiving treatment with H.P. Acthar Gel other side effects can happen that are like side effects that happen due to treatment with steroid medicines. The risk of getting side effects may increase the longer your child is treated with H.P. Acthar Gel. Side effects may include:

- **increased blood pressure.** Your doctor may check your child's blood pressure during treatment. If your child's blood pressure increases, your doctor may talk with you about possible treatment choices.
- **too much water in the body (water retention), increased amount of body salts, and low potassium in the blood.** H.P. Acthar Gel may cause your child to have an increased amount of body salts and water that stays in the body, and may lower the amount of potassium in your child's blood. Follow your doctor's instructions about if you need to decrease your child's salt intake or if you need to feed your child foods high in potassium.

4. Your child should not receive certain vaccines during treatment with H.P. Acthar Gel. Your child may receive killed or inactivated vaccines while receiving Acthar Gel. Before your child receives any vaccines, talk to your doctor about which vaccines are safe for your child. Certain vaccines could cause your child to have serious side effects, or the vaccine may not be effective.

5. Hiding (masking) symptoms of other conditions or diseases. It may be more difficult for your doctor to diagnose other conditions or diseases in your child during treatment with H.P. Acthar Gel. During treatment and after treatment ends, tell your doctor if your child has:

- any signs or symptoms of infection. See number 1 of this section in the Medication Guide.
- changes in body weight
- bloody or black tarry stool
- vomiting
- stomach pain
- excessive tiredness
- increased thirst
- fast heart rate
- difficulty breathing

6. Stomach and intestinal problems. H.P. Acthar Gel may cause bleeding of the stomach or intestine. Your child has an increased risk for bleeding from the stomach or having a stomach ulcer. . Tell your doctor if your child has any pain in the stomach area (abdominal pain), vomits blood, or has bloody or black stools.

7. Changes in mood and behavior. During treatment with H.P. Acthar Gel your child may be irritable, have rapid changes in his or her mood, be depressed, have other changes in his or her behavior, or have trouble sleeping.

Tell your doctor if your child has any of the side effects or symptoms listed above.

What is H.P. ACTHAR GEL?

H.P. Acthar Gel is a prescription medicine that is used to treat infantile spasms in infants and children under 2 years of age.

What should I tell my doctor before my child takes H.P. ACTHAR GEL?

Before your child takes H.P. Acthar Gel, read the section above “What is the most important information I should know about H.P. Acthar Gel?” and tell your doctor if your child has:

- an infection
- Diabetes
- heart problems
- kidney problems
- stomach or intestinal problems
- thyroid problems
- liver problems
- neuromuscular problems
- convulsions or seizures
- had exposure to someone with Tuberculosis (TB)
- a previous allergic reaction such as hives, itching or trouble breathing, to H.P. Acthar Gel or pork products
- had recent surgery
- had a recent vaccination or is scheduled to receive a vaccination
- a family member who is receiving vaccinations

Tell your doctor about all the medicines your child takes, including prescription and non-prescription medicines, vitamins and herbal supplements. Do not start giving a new medicine to your child without first speaking to your doctor.

How should I give H.P. Acthar Gel to my child? H.P. Acthar Gel is given as an injection into the muscle. Do not inject it under the skin, into a vein, or give it to your child by mouth.

- Inject H.P. Acthar Gel exactly as your doctor tells you. Your doctor will tell you where to give the injection, how much to give, how often and when to give it to your child.
- Do not use H.P. Acthar Gel until your doctor has taught you how to give the injection to your child.
- To give H.P. Acthar Gel:
 - Take the bottle from the refrigerator. Do not open the bottle or pry the cap (rubber stopper) off.
 - Warm the contents by rolling the bottle between your hands for a few minutes.
 - Wash your hands.

- Prepare the skin where you are going to give the injection by wiping it with a new sterile alcohol wipe. Before giving the injection, look at the site prepared for the injection and make sure that it no longer looks wet. A wet site can cause burning.
 - Wipe the top of the vial rubber stopper with a new sterile alcohol wipe.
 - Use a new sterile needle and syringe to draw up the amount of H.P. Acthar Gel the doctor has told you to use.
 - Give the injection the way the doctor has instructed you.
 - Return the bottle to the refrigerator as soon as possible.
- **Keep all of your child's follow-up appointments with your doctor**
- It is important for you to tell your doctor if your child's spasms continue or change in any way during treatment or after treatment has stopped so that they can monitor your child's progress.

Infantile Spasms sometimes hides (masks) other seizures your child or infant may have. Once treated with H.P. Acthar Gel, the Infantile Spasms symptoms may disappear. This may allow the other seizures to become visible for the first time. Tell your child's doctor right away if you see a change in your child's seizures/spasms.

What are the possible side effects of H.P. Acthar Gel?

H.P Acthar Gel can cause serious side effects.

- **See "What is the most important information I should know about Acthar Gel."**
- **H.P. Acthar Gel may make certain other medical conditions worse, such as diabetes (may increase blood sugar).**
- **Eye problems.** Your child can get cataracts, increased pressure in the eye (glaucoma), and possible damage to the optic nerve if treated with H.P. Acthar Gel for a long time.
- **Allergic reactions to H.P. Acthar Gel.** Your child may have an allergic reaction to H.P. Acthar Gel. Allergic reactions may not happen until your child has received several injections of H.P. Acthar Gel. Tell your doctor right away if your child has any of the following signs of an allergic reaction:
 - skin rash
 - swelling of the face, tongue, lips, or throat
 - trouble breathing

- **Changes in growth and physical development.** H.P. Acthar Gel may affect your child's growth and physical development and may weaken his or her bones. This is more likely to happen with long term use of Acthar Gel.
- **Enlarged heart.** H.P. Acthar Gel may cause an increase in the size of your child's heart. This is more likely to happen with long term use of Acthar Gel but usually goes away after H.P. Acthar Gel is stopped.

Common side effects of Acthar Gel may include:

- infections
- increased blood pressure
- irritability and changes in behavior
- changes in appetite and weight
- diarrhea
- vomiting

These are not all the possible side effects of H.P. Acthar Gel. Tell your doctor if your child has any side effect that bothers them or does not go away. For more information ask your child's doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store H.P. ACTHAR GEL?

- Store vials of H.P. Acthar Gel in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Throw away any vials after the expiration date printed on the label.

Keep H.P. Acthar Gel and all other medicines out of the reach of children

General information About H.P. Acthar Gel

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use H.P. Acthar Gel for a condition for which it has not been prescribed. Do not give H.P. Acthar Gel to other people, even if they have the same symptoms. It may harm them.

This Medication Guide summarizes the most important information about H.P. Acthar Gel. If you would like more information, talk with your child's doctor. You can ask your child's doctor or pharmacist for information about H.P. Acthar Gel that is written for healthcare professionals. For more information, go to www.acthar.com or call 1-800-465-9217.

What are the ingredients in H.P. Acthar Gel?

Active ingredient: Corticotropin

Inactive ingredients: gelatin, phenol, cysteine, sodium hydroxide and/or acetic acid to adjust pH, and water for injection

Manufactured for:
Questcor Pharmaceuticals, Inc.
3260 Whipple Road
Union City, CA 94587 USA

PL122/ Rev. 00
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This Medication Guide has been approved by the U.S. Food and Drug Administration.

H.P. Acthar[®] Gel is a registered trademark of Questcor Pharmaceuticals, Inc.

00165-JSC Document 1-6 Filed 01/08/21 Pa

No. 1350 PL063/Rev. 04

Warm before using.
Directions for use: see insert.
Each mL contains: 80 USP units corticotropin, 16% gelatin, 0.5% phenol, not more than 0.1% cysteine (added), sodium hydroxide and/or acetic acid to adjust pH, and water for injection, q.s.

5 mL multiple dose vial NDC 63004 7731 1

H.P.* Acthar® Gel
(repository corticotropin injection)
80 USP UNITS PER mL
FOR INTRAMUSCULAR OR SUBCUTANEOUS USE
Dispense the enclosed Medication Guide to each patient
Store in refrigerator, 2°-8°C (36°-46°F).
Rx only ***HIGHLY PURIFIED**
Questcor Pharmaceuticals, Inc.
Union City, CA 94587 USA

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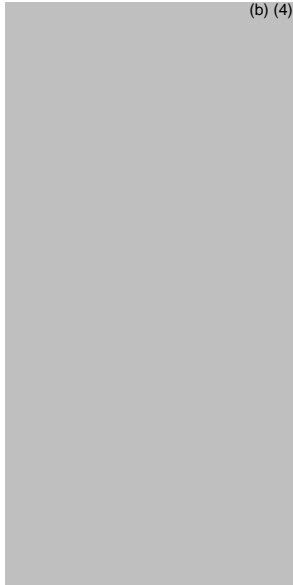
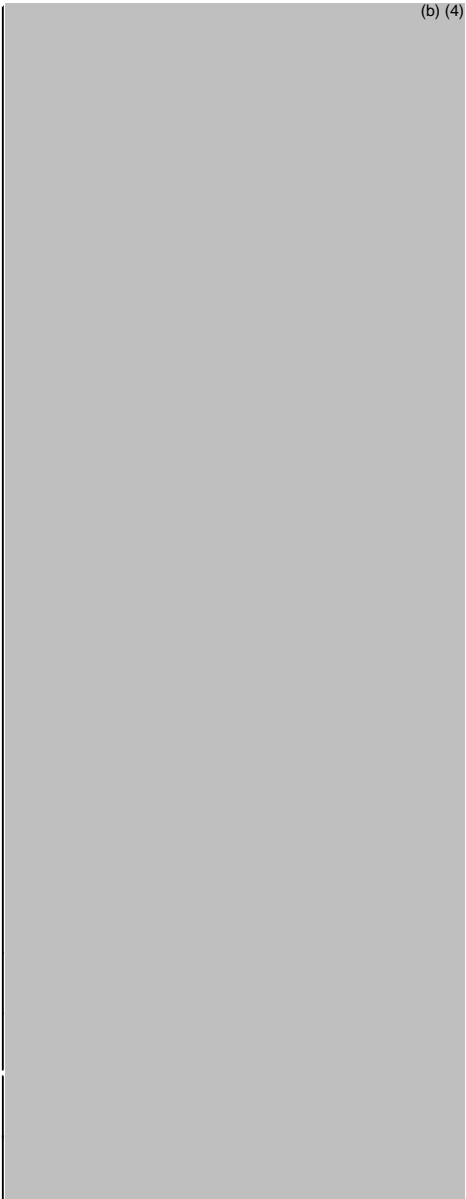
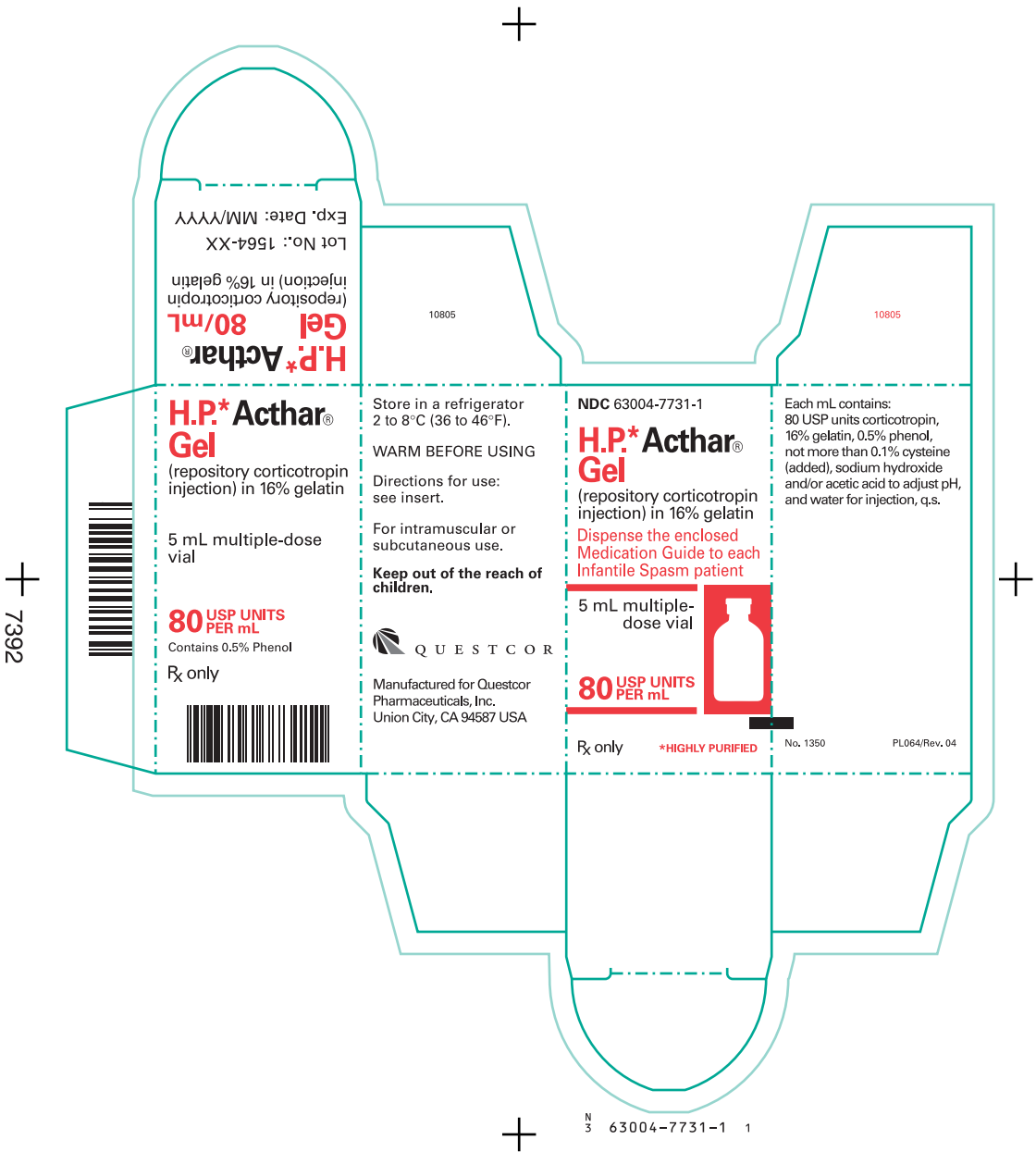


EXHIBIT H

JUSTICE NEWS

Department of Justice

Office of Public Affairs

FOR IMMEDIATE RELEASE

Wednesday, September 4, 2019

Drug Maker Mallinckrodt Agrees to Pay Over \$15 Million to Resolve Alleged False Claims Act Liability for “Wining and Dining” Doctors

Pharmaceutical company Mallinckrodt ARD LLC (formerly known as Mallinckrodt ARD Inc. and previously Questcor Pharmaceuticals Inc. “Questcor”), has agreed to pay \$15.4 million to resolve claims that Questcor paid illegal kickbacks to doctors, in the form of lavish dinners and entertainment, to induce prescriptions of the company’s drug, H.P. Acthar Gel (Acthar) from 2009 through 2013.

The Federal Anti-Kickback Statute prohibits a pharmaceutical company from offering or paying, directly or indirectly, any remuneration — which includes money or any other thing of value — with the intent to induce a health care provider to prescribe a drug reimbursed by a federal health care program, including Medicare. This prohibition extends to such practices as “wining and dining” doctors to induce them to write Medicare prescriptions of a company’s products.

The government alleged that, from 2009 to 2013, twelve Questcor sales representatives marketing Acthar provided illegal remuneration to health care providers in the form of lavish meals and entertainment expenses. The company paid this remuneration, the government alleges, with the intent to induce Acthar Medicare referrals from those health care providers, resulting in a violation of the Anti-Kickback Statute and the submission of false claims to Medicare.

“The Department of Justice will hold companies accountable for the payment of illegal kickbacks in any form,” said Assistant Attorney General Jody Hunt of the Department of Justice’s Civil Division. “Improper inducements have no place in our federal healthcare system, which depends on physicians making decisions based on the healthcare needs of their patients and not on or influenced by personal financial considerations.”

“When companies buy off doctors, patients suffer. My Office is committed to rooting out this type of behavior and the Anti-Kickback Statute is a critical tool in that fight,” said U.S. Attorney McSwain. “We will continue to protect the integrity of our healthcare system by holding drug companies accountable for their conduct.”

“Paying kickbacks to win business, as contended in this case, cheats taxpayers and the patients who rely on government health care programs for essential care,” said Maureen R. Dixon, Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services. “We will continue working with our law enforcement partners to hold accountable entities paying such kickbacks.”

The allegations that are the subject of yesterday’s settlement were originally alleged in two cases filed under the whistleblower, or qui tam, provision of the False Claims Act. The act permits private parties to sue for fraud on behalf of the United States and to share in any recovery. The act also permits the government to intervene in such actions, as the government previously did in the two whistleblower cases.

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The whistleblowers will receive approximately \$2.926 million of the settlement. The government is continuing to pursue claims in these two matters alleging that Mallinckrodt violated the False Claims Act by using a foundation as a conduit to pay illegal kickbacks in the form of copay subsidies for Acthar. These claims are not being resolved by the settlement.

The government's pursuit of these matters illustrates the government's emphasis on combating healthcare fraud. One of the most powerful tools in this effort is the False Claims Act. Tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement can be reported to the Department of Health and Human Services, at 800-HHS-TIPS (800-447-8477).

This matter is being handled by the Civil Division's Commercial Litigation Branch and the U.S. Attorney's Office for the Eastern District of Pennsylvania, with assistance from the U.S. Department of Health and Human Services Office of Inspector General. The two lawsuits are captioned *United States of America ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, No. 12-CV-0175 (E.D. Pa.) and *United States of America ex rel. Clark v. Questor Pharmaceuticals, Inc.*, No. 13-CV-1776 (E.D. Pa.).

The claims resolved by this settlement are allegations only and there has been no determination of liability.

Topic(s):

False Claims Act

Component(s):

Civil Division

USAO - Pennsylvania, Eastern

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EXHIBIT I



Original Investigation | Health Policy

Industry Payments to Physician Specialists Who Prescribe Repository Corticotropin

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Abstract

IMPORTANCE Despite great expense and little evidence supporting use over corticosteroids, prescriptions for repository corticotropin (H. P. Acthar Gel; Mallinckrodt Pharmaceuticals) have increased markedly. Aggressive sales tactics and payments from the manufacturer may influence prescribing behavior for this expensive medication.

OBJECTIVE To characterize industry payments to physician specialists who prescribe corticotropin in the Medicare program.

DESIGN, SETTING, AND PARTICIPANTS This study was a cross-sectional analysis of Centers for Medicare & Medicaid Services 2015 Part D prescribing data linked to 2015 Open Payments data. Nephrologists, neurologists, and rheumatologists with more than 10 corticotropin prescriptions (frequent prescribers) in 2015 were included.

EXPOSURES Frequency, category, and magnitude of corticotropin-related payments from Mallinckrodt recorded in the Open Payments database.

MAIN OUTCOMES AND MEASURES Frequency, category, and magnitude of corticotropin-related payments from Mallinckrodt, as well as corticotropin prescriptions and expenditures for Medicare beneficiaries.

RESULTS Of the 235 included physicians, 65 were nephrologists; 59, neurologists; and 111, rheumatologists. A majority of frequent corticotropin prescribers (207 [88%]) received corticotropin-related payments from Mallinckrodt. The median (range) total payment for 2015 was \$189 (\$11-\$138 321), with the highest payments ranging from \$56 549 to \$138 321 across the specialties. More than 20% of frequent prescribers received more than \$10 000 and the top quartile of recipients received a median (range) of \$33 190 (\$9934-\$138 321) in total payments per prescriber. Payments for compensation for services other than consulting contributed the most to the total amount. Mallinckrodt payments were positively associated with greater Medicare spending on corticotropin ($\beta = 1.079$; 95% CI, 1.044-1.115; $P < .001$), with every \$10 000 in payments associated with a 7.9% increase (approximately \$53 000) in Medicare spending on corticotropin. There was no association between corticotropin-related payments and spending on prescriptions for synthetic corticosteroids.

CONCLUSIONS AND RELEVANCE In this study, most nephrologists, neurologists, and rheumatologists who frequently prescribe corticotropin received corticotropin-related payments from Mallinckrodt. These findings suggest that financial conflicts of interest may be driving use of corticotropin in the Medicare program.

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Key Points

Question What is the association of industry payments to physicians and prescriptions for repository corticotropin (H. P. Acthar Gel; Mallinckrodt Pharmaceuticals)?

Findings In this cross-sectional study of 235 specialist physicians who frequently prescribe corticotropin to Medicare beneficiaries, 207 (88%) received a monetary payment from the drug's maker, with more than 20% of frequent prescribers receiving more than \$10 000. There was a significant association between higher dollar amounts paid to these prescribers and greater Medicare spending on their corticotropin prescriptions.

Meaning Financial conflicts of interest among physicians may be driving corticotropin expenditures for the Medicare program.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

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Introduction

It is well documented that the pharmaceutical industry spends a substantial amount of money to influence the decisions of physicians who use their products.^{1,2} In 2016, pharmaceutical, biotechnology, and device manufacturers paid 631 000 physicians more than \$2 billion in food and beverages, gifts, educational materials, and speaker and consulting services.³ Although physicians often deny these payments affect their prescribing decisions, the evidence suggests the contrary.⁴⁻¹¹ Studies consistently demonstrate pharmaceutical industry payments are associated with more prescriptions, greater prescription costs, and higher branded drug prescribing.^{5,9,11,12} Furthermore, several well-designed studies have demonstrated association specificity and a response gradient (higher payments associated with greater prescribing), suggesting the association is causal.^{5,7,10}

As high-priced therapies become the norm for many conditions, it is imperative that prescribing decisions are evidence based and free from undue commercial influence. Expensive therapies with uncertain or insufficient evidence supporting their use should be particularly scrutinized. A prime example of such a treatment is repository corticotropin (H. P. Acthar Gel; Mallinckrodt Pharmaceuticals). Originally approved by the US Food and Drug Administration (FDA) in 1952, corticotropin has received considerable attention in recent years because of the dramatic increase in its cost. Corticotropin is a porcine-derived biologic preparation with a proprietary manufacturing process and for decades was available for less than \$50 per vial. In 2007, Questcor Pharmaceuticals, who acquired the license for corticotropin in 2001 for \$100 000, raised the acquisition price for a 5-mL vial from \$1650 to \$23 269 (a 14-fold increase).¹³ Mallinckrodt Pharmaceuticals, which acquired Questcor in 2014, has continued to raise the price to its current acquisition cost of \$38 892.¹⁴

There is a lack of evidence supporting the use of corticotropin for most indications.¹⁵ Corticotropin was approved prior to the 1962 Kefauver-Harris Amendment to the US Food, Drug, and Cosmetics Act, which added the requirement of evidence of efficacy to the FDA approval process.¹⁶ As a consequence, corticotropin's original label lacked evidence derived from controlled clinical trials that meet current standards for FDA approval for any indication. Over the ensuing years, corticotropin's label has been revised several times, first as part of the FDA's Drug Efficacy Study Implementation review in 1971, and then with the addition of indications for the treatment of relapses of multiple sclerosis in 1979 and infantile spasms in 2010.¹⁷ The only randomized clinical trials of corticotropin to treat relapses of multiple sclerosis show it to be more effective than placebo (n = 197) but no better than methylprednisolone (n = 61).^{18,19} The use of corticotropin for infantile spasms is supported by 5 controlled clinical trials of between 24 and 50 (mean, 34) participants.²⁰⁻²⁴ Corticotropin is also indicated and promoted on its website for systemic lupus erythematosus, proteinuria in nephrotic syndrome, dermatomyositis and polymyositis, rheumatoid arthritis, symptoms of sarcoidosis, and inflammatory conditions of the eye, such as uveitis. With the exception of a small placebo-controlled trial of 38 individuals with systemic lupus erythematosus demonstrating equivocal efficacy compared with placebo,²⁵ the clinical evidence supporting the efficacy of corticotropin for these indications generally consists of small (n < 25) uncontrolled trials and case reports.²⁶

Because of its very high price, corticotropin is a major expenditure for public insurance programs in the United States. From 2011 to 2015, spending on corticotropin in the US Medicare program increased 10-fold, totaling more than \$1 billion during this period.²⁷ In 2015 alone, Medicare spent more than \$500 million on corticotropin, making it one of the most expensive drugs paid for by the program.²⁸ The continued growth in corticotropin use is peculiar given its very high cost, widespread negative media coverage, and notable lack of evidence supporting its use over lower-cost synthetic corticosteroids.^{29,30} Our experience suggests aggressive marketing of the drug partly accounts for increasing use. While media reports also indicate that industry payments to corticotropin prescribers may have a role, the prevalence, magnitude, and effect of corticotropin-related payments have not been systematically described.³⁰ The goal of this research was to

characterize payments to physicians who frequently prescribe corticotropin to Medicare beneficiaries and determine whether payment amounts are positively correlated with prescribing intensity.

Methods

Study Sample and Data Sources

Using several publicly accessible databases provided by the Centers for Medicare & Medicaid Services (CMS), we conducted a cross-sectional study to describe pharmaceutical industry payments to nephrologists, neurologists, and rheumatologists who frequently prescribe corticotropin in the Medicare Part D program. To identify Medicare prescribers of corticotropin, we used Medicare Part D Public Use Files (PUFs) from 2015.³¹ Medicare Part D PUFs contain prescription information aggregated at different levels for drugs paid for by Medicare Part D stand-alone plans and Medicare Advantage plans and include data for 71% of all 56 million Medicare beneficiaries.²⁸ The Detailed Prescriber PUF summarizes total prescriptions and costs for every drug with more than 10 prescriptions by a prescriber. We used the Detailed Prescriber PUF to identify and determine the specialty of physicians who prescribed corticotropin in 2015. Drugs with 10 or fewer prescriptions per prescriber are suppressed by CMS to protect patient confidentiality. We focused on rheumatology, neurology, and nephrology specialists, who are the largest prescribers of corticotropin.²⁷ Because this study used publicly available data, the Oregon Health & Science University institutional review board deemed it exempt from review. Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guidelines were followed.

To summarize characteristics of these frequent corticotropin prescribers, we used the Medicare Part D Prescriber PUF and data from CMS Physician Compare. The Part D Prescriber PUF contains drug utilization data (eg, total prescriptions, beneficiaries, and expenditures for Medicare) for all participating Part D prescribers. We used the CMS Physician Compare data set to characterize other practice-related data, such as year of graduation from medical school and practice size. The CMS Physician Compare data set contains general demographic, training, and practice site information for all health care professionals who provide Medicare services. For comparison, we also summarized Part D prescribing and practice characteristics for all other neurologists, rheumatologists, and nephrologists who provide Medicare services.

To obtain information on industry payments, we used 2015 calendar year files from the Open Payments website. The Open Payments program began collecting information about payments from drug and device companies to physicians and teaching hospitals in 2013.³² Reported payments include consulting fees, honoraria, gifts, entertainment, food and beverage, travel, and research payments and ownership interests.³³ All payments with a cash value of at least \$10, or \$100 in aggregate in 1 calendar year, must be reported. The payment data also report the specific product (eg, drugs, devices, biologics) to which the payment was related.

For corticotropin prescribers identified in the Medicare Part D PUF, we manually reviewed his or her Open Payments physician demographic characteristics record to verify concordance. While PUFs are indexed by each prescriber's National Prescriber Identifier, Open Payments only includes name and location as identifiers. If prescriber specialty differed between the Medicare Part D PUF and Open Payments data, we used CMS Physician Compare data to verify the physician's specialty. If a prescriber was not found within Open Payments, we verified their specialty in Physician Compare and considered them to not have received any industry payments. Only 1 prescriber's specialty designation was misclassified in the Medicare PUF.

After we verified the linkage between each corticotropin prescriber and his or her Open Payments record, we extracted information from the Open Payments data on total payment amounts, number of transactions, and types of payments from Mallinckrodt Pharmaceuticals in 2015. We only included Mallinckrodt payments if the payment indicated it was for corticotropin. Our analysis included general payments (eg, honoraria or consulting), research payments, and ownership

payments. We also extracted and summarized payments from Mallinckrodt unrelated to corticotropin and all other companies.

Statistical Analysis

We analyzed the prevalence, frequency, category, and monetary amount of corticotropin-related payments by Mallinckrodt. Physician and payment characteristics were summarized with descriptive statistics as appropriate depending on their nature and distribution.

We evaluated the association between payment amounts and Medicare expenditures on corticotropin in 2 ways. First, we grouped prescribers into categories by the total dollar amounts of corticotropin-related payments received from Mallinckrodt and examined the trend in total corticotropin prescriptions and expenditures using the Kendall rank correlation coefficient statistic (Kendall τ). We also conducted multivariable linear regression analyses to evaluate whether payment amounts were positively correlated with corticotropin Medicare expenditures. Our dependent variable was the dollar amount that Medicare spent on corticotropin. The primary independent variable was the total Mallinckrodt corticotropin-related payment to these specialists. Similar to DeJong et al,⁷ we controlled for the following covariates: physician specialty, sex, group practice size, years since graduation from medical school, and geographic region. To adjust for differences in other prescribing behaviors, we included covariates measuring the number of noncorticotropin prescriptions per beneficiary and the cost of noncorticotropin prescriptions per claim. We also adjusted for total payments unrelated to corticotropin from industry (eg, payments from other companies) to control for differences in engagement with other companies. For our primary analysis, we transformed the dependent variable with natural logarithmic transformation because Medicare spending data were right skewed. Relative to an untransformed model, using a logarithmic-transformed dependent variable resulted in improved model fit and diagnostic performance.

Finally, to assess the specificity of the association between corticotropin-related payments and corticotropin spending, we conducted a falsification test to evaluate the association between corticotropin-related payments and synthetic corticosteroid spending. Using the same modeling approach, we tested the association between corticotropin-related payments and spending for prednisone, methylprednisolone, prednisolone, dexamethasone, and cortisone. A positive relationship between corticotropin-related payments and corticosteroid spending would suggest any observed association between corticotropin-related payments and corticotropin spending may be confounded by other factors, such as patient severity of illness. For prescribers with no recorded corticosteroid spending, we imputed 0.001 before performing log transformation.

Analyses were conducted using SAS statistical software, version 9.4 (SAS Institute), and R statistical software, version 3.3.3 (R Foundation for Statistical Computing). All tests were 2-sided and *P* values less than .05 were considered statistically significant.

Results

In 2015, Medicare spent \$504 million for 11 209 corticotropin prescriptions written by 1743 prescribers. More than half of this expenditure (\$266 197 661) was attributable to 300 prescribers (17.2%) with more than 10 corticotropin prescriptions. Most of these prescribers (*n* = 235) were identified, and verified, as rheumatologists (*n* = 111), neurologists (*n* = 59), or nephrologists (*n* = 65). Of the remaining 65 frequent prescribers, 24 were listed as internists, 19 were pulmonologists, 8 had other specialty designations (1 each for allergy and immunology, dermatology, diagnostic radiology, emergency medicine, family practice, neurosurgery, ophthalmology, and pain management), and 14 were other midlevel practitioners (9 nurse practitioners and 5 physician assistants).

The characteristics of the 235 frequent corticotropin prescribers and all other Medicare prescribers in their specialty groups (*n* = 26 046) are summarized in **Table 1**. In 2015, Medicare spent a total of \$203 255 335 for corticotropin prescribed by these 235 physicians (median [interquartile range], \$678 706 [\$465 974-\$984 020] per prescriber). Expenditures for corticotropin among

Table 1. Characteristics of Frequent Prescribers of Repository Corticotropin in the Medicare Program in 2015

Characteristic	Nephrology		Neurology		Rheumatology		All 3 Specialties	
	Frequent Corticotropin Prescribers (n = 65)	Other Prescribers (n = 8213)	Frequent Corticotropin Prescribers (n = 59)	Other Prescribers (n = 13 325)	Frequent Corticotropin Prescribers (n = 111)	Other Prescribers (n = 4508)	Frequent Corticotropin Prescribers (n = 235)	Other Prescribers (n = 26 046)
Male, No. (%)	50 (76.9)	6085 (74.1)	41 (69.5)	9305 (69.8)	74 (66.7)	2626 (58.3)	165 (70.2)	18 016 (69.2)
Group practice size, No. (%)								
1	12 (18.5)	1068 (13.0)	22 (37.3)	2647 (19.9)	33 (29.7)	965 (21.4)	67 (28.5)	4680 (18.0)
2-10	22 (33.8)	1999 (24.3)	9 (15.3)	1509 (11.3)	35 (31.5)	735 (16.3)	66 (28.1)	4243 (16.3)
11-50	18 (27.7)	1747 (21.3)	8 (13.6)	1252 (9.4)	10 (9.0)	389 (8.6)	36 (15.3)	3388 (13.0)
>50	13 (20.0)	3399 (41.4)	20 (33.9)	7917 (59.4)	33 (29.7)	2419 (53.7)	66 (28.1)	13 735 (52.7)
Time since graduation, mean (SD), y ^a	23.5 (10.5)	22.9 (11.2)	26.6 (9.4)	23.4 (12.1)	26.6 (10.5)	24.4 (12.1)	25.7 (10.3)	23.4 (11.8)
US geographic region, No. (%)								
Northeast	13 (20.0)	1720 (20.9)	9 (15.3)	3267 (24.5)	25 (22.5)	1083 (24.0)	47 (20.0)	6070 (23.3)
Midwest	10 (15.4)	1723 (21.0)	12 (20.3)	2885 (21.7)	24 (21.6)	956 (21.2)	46 (19.6)	5564 (21.4)
South ^b	33 (50.8)	3118 (38.0)	24 (40.7)	4478 (33.6)	42 (37.8)	1563 (34.7)	99 (42.1)	9159 (35.2)
Pacific West	7 (10.8)	1117 (13.6)	8 (13.6)	1896 (14.2)	14 (12.6)	658 (14.6)	29 (12.3)	3671 (14.1)
Mountain West	2 (3.1)	535 (6.5)	6 (10.2)	799 (6.0)	6 (5.4)	248 (5.5)	14 (6.0)	1582 (6.1)
Corticotropin prescribing								
Total corticotropin expenditure, \$	41 665 749	NR	41 056 933	NR	120 532 653	NR	203 255 335	NR
Corticotropin expenditure per prescriber, median (IQR), \$	506 718 (420 884-659 918)	NR	614 760 (443 558-737 420)	NR	824 545 (591 100-1 172 163)	NR	678 706 (465 974-984 020)	NR
Corticosteroid prescribing ^c								
Count of frequent prescribers, No. (%)	49 (75.4)	4375 (53.2)	37 (62.7)	3890 (29.2)	111 (100)	4378 (97.1)	197 (83.8)	12 643 (48.5)
Total corticosteroid expenditure, \$	24 782	1 802 668	62 551	1 774 892	1 145 859	23 071 018	1 233 192	26 648 578
Corticosteroid expenditure per prescriber, median (IQR), \$	273 (146-273)	241 (140-440)	825 (313-1856)	279 (161-516)	6043 (3210-6043)	3607 (1660-6470)	2444 (460-6899)	450 (199-2113)
All medication prescribing								
Total expenditure, \$	75 789 407	2 531 033 434	197 296 370	6 974 756 737	275 778 740	3 444 695 122	548 864 517	12 950 485 292
Expenditure per prescriber, median (IQR), \$	1 035 563 (702 181-1 335 092)	220 798 (84 500-412 292)	3 000 411 (2 002 159-3 990 935)	245 589 (43 037-662 864)	2 299 877 (1 556 368-3 070 141)	584 817 (252 536-1 037 950)	1 932 495 (1 168 339-3 008 416)	275 396 (77 177-639 819)
Prescriptions per prescriber, median (IQR), No.	2373 (1604-3607)	1432 (642-2532)	3803 (2152-6630)	999 (278-2266)	3801 (2520-5501)	1967 (910-3593)	3377 (2105-5501)	1301 (451-2584)
Expenditure per prescription, median (IQR), \$	380 (305-530)	144 (93-213)	677 (450-1322)	210 (113-358)	604 (436-758)	285 (196-396)	530 (378-823)	195 (113-321)

Abbreviations: IQR, interquartile range; NR, not reported.

^a Graduation year missing for 4.3% of corticotropin prescribers and 6.2% of other prescribers.^b One physician from Puerto Rico was categorized into South.^c Corticosteroids include prednisone, methylprednisolone, prednisolone, dexamethasone, and cortisone.

frequent prescribers accounted for 37% of their total Part D expenditures, but ranged from 21% for neurologists to 54% for nephrologists. Frequent corticotropin prescribers were more likely to practice in smaller practices, write more prescriptions, and prescribe more expensive drugs than their specialty peers. Frequent corticotropin prescribers also prescribed more synthetic corticosteroids than their peers. Of these 235 physician prescribers of corticotropin, 25 (11%) practiced within an academic medical center.

In 2015, Mallinckrodt paid \$11 442 866 (\$7 325 957 in general payments and \$4 116 908 in research payments) to 10 491 physicians for corticotropin (10 452 for general payments and 97 for research payments). Among frequent corticotropin prescribers in our study, Mallinckrodt made a total of 5315 corticotropin-related payments to 207 prescribers (88% of frequent corticotropin specialist prescribers), totaling \$2 213 727 (\$1 986 926 in general payments and \$226 801 in research payments). **Table 2** summarizes the distribution and types of corticotropin-related payments made by Mallinckrodt to these frequent prescribers. Most nephrologists and nearly all neurologists and rheumatologists received at least 1 corticotropin-related payment from Mallinckrodt. Overall, while the median (range) total payment amounts during the year were modest at \$189 (\$11-\$138 321), maximum total payment amounts were as high as \$56 549 for nephrology, \$120 387 for neurology, and \$138 321 for rheumatology. The median (range) total payment for the top quartile of the 207 prescribers who received at least 1 payment was \$33 190 (\$9934-\$138 321) overall, but ranged from \$5249 for nephrologists to \$41 405 for neurologists. Neurologists were the most likely to receive a payment (93.2% vs 78.5% for nephrologists and 91.0% for rheumatologists), had the greatest number of transactions (20 vs 5 for nephrologists and 13 for rheumatologists), and received the highest median total dollar amount over the year (\$476 vs \$118 for nephrologists and \$207 for rheumatologists). Differences in total payments were driven by a higher likelihood of consulting,

Table 2. Repository Corticotropin-Related Payments to Frequent Physician Prescribers of Corticotropin From Mallinckrodt in 2015

Payments	Nephrology (n = 65)	Neurology (n = 59)	Rheumatology (n = 111)	Total (n = 235)
Any payment type				
Prescribers, No. (%)	51 (78.5)	55 (93.2)	101 (91.0)	207 (88.1)
Total payments, \$	180 621	878 069	1 155 038	2 213 727
Total payments per prescriber, median (range), \$	118 (12-56 549)	476 (11-120 387)	207 (12-138 321)	189 (11-138 321)
Total transactions, No.	517	2219	2579	5315
Transactions per prescriber, median (range), No.	5 (1-86)	20 (1-236)	13 (1-199)	11 (1-236)
Payment per transaction, median (range), \$	22 (12-767)	28 (6-722)	22 (5-3671)	23 (5-3671)
Specific payment category				
Compensation for services other than consulting				
Prescribers, No. (%)	7 (10.8)	24 (40.7)	32 (28.8)	63 (26.8)
Total payments per prescriber, median (range), \$	12 900 (2200-37 450)	15 865 (1990-91 400)	14 100 (650-70 650)	14 700 (650-91 400)
Travel				
Prescribers, No. (%)	6 (9.2)	21 (35.6)	33 (29.7)	60 (25.5)
Total payments per prescriber, median (range), \$	5579 (62-14 690)	4253 (183-29 508)	2034 (10-28 061)	3213 (10-29 508)
Consulting				
Prescribers, No. (%)	4 (6.2)	20 (33.9)	26 (23.4)	50 (21.3)
Total payments per prescriber, median (range), \$	2863 (1500-7500)	2700 (400-7400)	2680 (2500-15 860)	2700 (400-15 860)
Research				
Prescribers, No. (%)	2 (3.1)	6 (10.2)	4 (3.6)	12 (5.1)
Total payments per prescriber, median (range), \$	4833 (4010-5656)	407 (407-819)	53 208 (32 865-75 000)	2415 (407-75 000)
Food				
Prescribers, No. (%)	51 (78.5)	55 (93.2)	101 (91.0)	207 (88.1)
Total payments per prescriber, median (range), \$	118 (12-1184)	273 (11-2068)	206 (12-2773)	183 (11-2773)
Education				
Prescribers, No. (%)	11 (16.9)	16 (27.1)	25 (22.5)	52 (22.1)
Total payments per prescriber, median (range), \$	5 (1-18)	5 (1-41)	8 (3-78)	7 (1-78)

travel, and compensation for services other than consulting. Payments to neurologists for services other than consulting contributed the most to this difference (median [range] total payment amount, \$15 865 [\$1990-\$91 400]). Research-related payments totaled \$226 801 for 12 prescribers (5.1%). They were particularly high for 4 rheumatologists, who received a total of \$214 281 (median [range], \$53 208 [\$32 865-\$75 000]) during the year. No prescribers received ownership-related payments. As shown in eTable 1 in the [Supplement](#), payments to these prescribers unrelated to corticotropin were also common and substantial.

In **Table 3** and the **Figure**, we summarize corticotropin use by corticotropin-related payment amount categories. Among the 50 prescribers (21.3%) who received more than \$10 000 in payments during the year, corticotropin expenditures per prescriber (mean [SD], \$1 304 884 [\$1 022 937]) were more than double that of the 45 prescribers (19.2%) who received \$25 dollars or less (mean [SD], \$594 976 [\$256 357]). There were 4 prescribers who received more than \$100 000 in payments from Mallinckrodt. There were significant associations between payment amount category and corticotropin expenditures (Kendall $\tau = 0.29$; $P < .001$) and payment amount category and number of prescriptions (Kendall $\tau = 0.252$; $P < .001$) among these frequent prescribers.

Our multivariable regression analysis is summarized in **Table 4** and shows that Medicare spending on corticotropin increased by 7.9% (approximately \$53 000) for every \$10 000 increase in payments to prescribers ($\beta = 1.079$; 95% CI, 1.044-1.115; $P < .001$). The only other significant predictors of Medicare spending on corticotropin were prescriber specialty and sex. In contrast, there was no association between corticotropin-related payments and Medicare spending on corticosteroids (eTable 2 in the [Supplement](#)).

Discussion

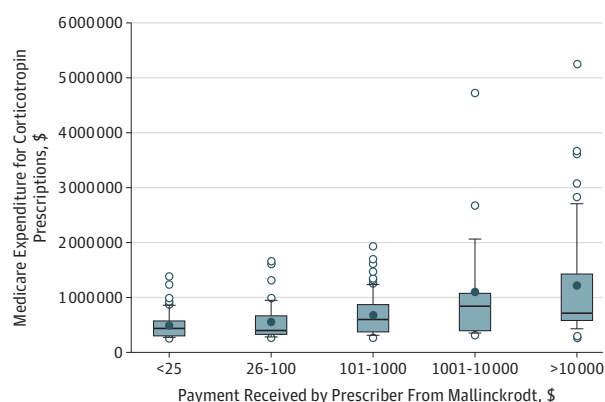
In our study, 207 of 235 frequent corticotropin prescribers (88%) received a corticotropin-related payment from Mallinckrodt. In 2015, Mallinckrodt made a total of \$7 325 957 in general

Table 3. Medicare Repository Corticotropin Use by Corticotropin-Related Payment Level^a

Total Payments From Mallinckrodt, \$	Prescribers, No. (%)	Corticotropin Prescriptions, No.	Corticotropin Prescriptions per Prescriber, Mean (SD), No.	Total Corticotropin Expenditures, \$	Corticotropin Expenditures per Prescriber, Mean (SD), \$
≤25	45 (19.2)	700	15.6 (5.9)	26 773 924	594 976 (256 357)
26-100	41 (17.5)	644	15.7 (6.0)	26 854 807	654 995 (337 798)
101-1000	80 (34.0)	1458	18.2 (8.5)	61 828 987	772 862 (363 721)
1001-10 000	19 (8.1)	527	27.7 (24.1)	22 553 434	1 187 023 (1 038 448)
>10 000	50 (21.3)	1433	28.7 (21.6)	65 244 183	1 304 884 (1 022 937)

^a Significant associations between payment level and mean corticotropin prescriptions (Kendall $\tau = 0.252$; $P < .001$) and between payment level and mean corticotropin expenditures (Kendall $\tau = 0.29$; $P < .001$).

Figure. Medicare Spending on Repository Corticotropin by Mallinckrodt Payment Amount



The horizontal line in the middle of each box indicates median corticotropin spending per prescriber; bottom and top borders of the box, 25th and 75th percentiles, respectively; whiskers below and above the box, 10th and 90th percentiles; solid circle, mean corticotropin spending per prescriber; and open circles, outliers.

non-research-related corticotropin payments to 10 452 physicians. Of this amount, \$1 986 926 (27%) was paid to the 207 frequent corticotropin prescribers (2% of all physicians receiving Mallinckrodt payments for corticotropin) in our study. In contrast, a recent population-based study found that among all specialists, only 35% receive payments from industry.³⁴ Although the median total payment for the year was only \$189, more than 20% of prescribers received more than \$10 000, the top quartile of prescribers received more than \$30 000, and several physicians received more than \$100 000. The larger dollar amounts given to neurologists were attributable to a higher prevalence of consulting payments or compensation for services other than consulting among these specialists. In general, the category of compensation for services other than consulting had the largest dollar amount per transaction. This category is defined by CMS as “payments made to physicians for speaking, training, and education engagements that are not for continuing education.”³ Although precise definitions of reporting categories are not provided, this category likely includes serving on industry speakers’ bureaus and other activities that involve giving talks to physician groups. Finally, we found a significant association between the magnitude of payments and total corticotropin expenditures. Our analysis suggests that every \$10 000 spent by Mallinckrodt for payments to physicians is associated with a 7.9% increase in Medicare spending on corticotropin. Based on a median Medicare expenditure per prescriber of \$678 706, we would expect a \$10 000 increase in payments to yield approximately \$53 000 in additional Medicare spending.

Our findings are consistent with other research that examines both the prevalence and extent of influence of pharmaceutical industry payments on physicians. Three large cross-sectional studies that used a similar approach for other medications found that industry payments were positively correlated with increased drug-specific prescribing.⁷⁻⁹ These studies provide evidence that even small payments, such as meals, are consistently associated with increased prescribing behavior.

Table 4. Multivariable Regression Model of Cumulative Repository Corticotropin-Related Payments (Scaled to \$10 000) and Log-Transformed Medicare Spending on Corticotropin

Variable	Coefficient (95% CI)	P Value
Payment amount ^a	1.0787 (1.0435-1.1152)	<.001
Specialty		
Nephrology	1 [Reference]	
Neurology	0.9600 (0.7721-1.1936)	<.001
Rheumatology	1.4378 (1.2223-1.6913)	
Female	0.8554 (0.7422-0.9858)	.03
Practice size		
1	1 [Reference]	
2-10	1.1082 (0.9225-1.3314)	.31
11-50	0.9220 (0.7438-1.1429)	
>50	1.0645 (0.8871-1.2773)	
Time since graduation, y		
≤10	1 [Reference]	
11-30	1.1773 (0.8781-1.5786)	.49
>30	1.1906 (0.8744-1.6212)	
Not reported	1.4069 (0.9091-2.1772)	
Region		
Northeast	1 [Reference]	
Midwest	0.9585 (0.7814-1.1756)	.35
South	0.9045 (0.762-1.0736)	
Pacific West	1.0532 (0.8356-1.3275)	
Mountain West	0.8003 (0.596-1.0748)	
Total noncorticotropin payments from industry ^a	0.9972 (0.9999-1.0003)	.16
No. of noncorticotropin prescriptions per beneficiary	1.0060 (0.9901-1.0221)	.46
Cost of noncorticotropin prescriptions per claim	1.0001 (0.9934-1.0011)	.40

^a Scaled to \$10 000.

Additionally, studies focusing on payments by specific manufacturers in several medical specialties report results similar to our own. Two studies evaluating the use of anti-vascular endothelial growth factor injections for eye diseases found payments by Regeneron Pharmaceuticals and Genentech were associated with a higher likelihood of using aflibercept or ranibizumab, respectively, vs lower cost, off-label bevacizumab.^{10,35} Studies of the impact of industry payments on urologists or oncologists treating prostate cancer reveal similar patterns.^{6,36,37}

Our findings contrast with the prior literature arising from Open Payments data in several ways. First, about 90% of physicians who frequently prescribed corticotropin received at least 1 payment from Mallinckrodt. Among the ophthalmologists,¹⁰ urologists,³⁷ and oncologists³⁶ examined in recent studies of other expensive medications, only 34% to 57% of identified drug prescribers received a manufacturer-related payment. Additionally, payments by Mallinckrodt in the present study appear to be larger than the amounts reported in other studies. In this report, almost a third of frequent prescribers received more than \$1000 from Mallinckrodt. In contrast, only 3.8% of prescribers of anti-vascular endothelial growth factor received more than \$1000 from the associated manufacturer.¹⁰ While the reasons for this discrepancy are unclear, it may be attributable to the extent to which Mallinckrodt's product portfolio depends on corticotropin, which accounted for more than a third of total sales in 2016.³⁸ Alternatively, a higher-stakes sales approach may be required to compensate for the lack of compelling evidence justifying corticotropin use over standard synthetic steroids. The most common prescribers of corticotropin are rheumatologists, neurologists, and nephrologists,²⁷ suggesting the use of corticotropin in individuals with rheumatic disorders, multiple sclerosis, and nephrotic syndrome. Among these conditions, controlled clinical trial data only support corticotropin use to treat exacerbations of multiple sclerosis,^{18,19} although it is no more effective than methylprednisolone. The use of corticotropin for rheumatoid arthritis,³⁹ dermatomyositis and polymyositis,⁴⁰⁻⁴² systemic lupus erythematosus,^{25,43} and nephrotic syndrome⁴⁴⁻⁴⁸ is largely supported by small uncontrolled studies or case series.

Limitations

Our study has several limitations. First, CMS suppresses prescription information for drugs that have 10 or fewer prescriptions in the Medicare PUF files. Although frequent corticotropin prescribers account for more than half of all corticotropin expenditures by Medicare, it is unclear to what extent our observations generalize to the other 1443 corticotropin prescribers who cannot be identified in the data set. Another issue relates to the accuracy of the Open Payments and Medicare PUF data sets. The Centers for Medicare & Medicaid Services allows and recommends that physicians review payment data and dispute any errors in their records. However, residual inaccuracies may persist. Additionally, Medicare expenditure data do not include any proprietary discounts or rebates, and are therefore likely an overestimate of the net cost to Medicare. Rebates for corticotropin for Medicare are less than federal Medicaid mandatory rebates and are likely around 10%.³² Finally, although these data may indicate a causal association between Mallinckrodt payments and corticotropin prescriptions, our study was cross-sectional and the temporal sequence between payments and prescriptions cannot be definitely established. It is conceivable that the company preferentially sought out and supported prominent prescribers of corticotropin.

Conclusions

Corticotropin is an expensive drug of questionable clinical value that is a large and growing expense for the Medicare program, and perhaps other payers. Our results show that most frequent prescribers of corticotropin in the Medicare program received financial payments from Mallinckrodt, the drug's maker. Furthermore, we observed a positive association between the amount of money paid to these prescribers, their prescribing intensity, and corticotropin expenditures in the Medicare program with a return on investment for Mallinckrodt of about 5:1. Transparency remains a necessary part of conflict of interest management, and we advocate that physicians who receive significant

payments from Mallinckrodt disclose this to patients before prescribing corticotropin for them or consider not receiving any payments from Mallinckrodt. However, disclosure alone may not be sufficient. While academic medical institutions⁴⁹ have implemented conflict of interest policies intended to limit many of the activities observed in this study, those in private practice, like most prescribers in this study, are subject to little oversight. Given the financial consequences for many expensive therapies (both new and old), other stakeholders, including payers, may need to explore other strategies to manage these conflicts.

ARTICLE INFORMATION

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Author Contributions: Dr Hartung had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Hartung, Bourdette.

Acquisition, analysis, or interpretation of data: Hartung, Johnston, Cohen, Nguyen, Deodhar.

Drafting of the manuscript: Hartung, Johnston, Nguyen.

Critical revision of the manuscript for important intellectual content: Hartung, Cohen, Nguyen, Deodhar, Bourdette.

Statistical analysis: Hartung, Johnston, Nguyen.

Obtained funding: Hartung.

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Supervision: Hartung, Cohen, Nguyen, Deodhar.

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SUPPLEMENT.

eTable 1. Non-Repository Corticotropin (ACTH)-Related Payments to Frequent ACTH Prescribers From all Pharmaceutical Companies, Including Mallinckrodt, in 2015

eTable 2. Multivariable Regression Model of Cumulative Repository Corticotropin (ACTH)-Related Payments (Scaled to \$10,000) and Log-Transformed Medicare Spending on Corticosteroids

EXHIBIT J

**UNITED STATES DISTRICT COURT
 CENTRAL DISTRICT OF CALIFORNIA**

HUMANA INC.,
 Plaintiff,

v.

MALLINCKRODT ARD LLC
 (f/k/a Mallinckrodt ARD Inc., f/k/a
 Questcor Pharmaceuticals, Inc.),
 Defendant.

CV 19-06926 DSF (MRW)

Order GRANTING in part and
 DENYING in part Defendant's
 Motion to Dismiss and
 DENYING Defendant's Motion
 to Strike (Dkt. 47)

Defendant Mallinckrodt ARD LLC moves to dismiss Plaintiff Humana Inc.'s First Amended Complaint (FAC) in its entirety. Dkt. 47-1 (Mot.). Plaintiff opposes the Motion. Dkt. 51 (Opp'n). The Court deems this matter appropriate for decision without oral argument. See Fed. R. Civ. P. 78; Local Rule 7-15.

I. FACTUAL AND PROCEDURAL BACKGROUND

Defendant produces H.P. Acthar Gel (Acthar), a drug that was invented in 1948 and first approved by the FDA in 1952. Dkt. 46 (FAC) ¶¶ 2, 4, 42, 44. Plaintiff operates or administers Medicare Part D plans on behalf of federal and state governments and provides coverage for prescription drugs, including Acthar, through other plans. Id. ¶ 39. Acthar is an adrenocorticotrophic hormone (ACTH) used as an anti-inflammatory. Id. ¶ 41. Acthar is the only ACTH drug approved for sale in the United States. Id. ¶ 57. Another ACTH drug, Synacthen, is approved for sale outside of the United States. Id. ¶ 62. Acthar is approved to treat exacerbations of multiple sclerosis (MS) as well as other diseases and disorders. Id. ¶ 41. However, for many of these

conditions, Acthar is not the “first-line treatment.” Id. ¶ 46. Cheaper non-ACTH drugs are used to treat the same indications. Id. ¶¶ 57, 84. In 2010, the FDA approved Acthar for infantile spasms, the only condition for which Acthar is the “first-line treatment.” Id. ¶ 48. The only other FDA-approved drug for infantile spasms costs four times less than Acthar, although it is prescribed for a smaller set of patients. Id. ¶ 58.

Until 2001, when Defendant’s predecessor, Questcor, acquired worldwide rights to sell and manufacture Acthar for \$100,000, plus royalties, Acthar was priced competitively with other anti-inflammatory drugs. Id. ¶ 49. At that time, because Acthar was expensive to produce and not the first-line treatment for most conditions, the prior manufacturer considered discontinuing production. Id. However, as soon as Questcor acquired the rights to sell Acthar, it increased the price from approximately \$40 per vial to nearly \$750 per vial. Id. ¶ 51. On August 27, 2007, Questcor further increased the price from \$1,650 to \$23,269 per vial. Id. ¶ 52. By 2018, the price has been further increased to \$38,892. Id. ¶ 53. Between 2011 and 2015, net sales of Acthar increased from \$218 million to more than \$1 billion, and Medicare spending on Acthar increased from \$50 million to \$500 million. Id. ¶¶ 54-55. Humana itself paid more than \$700 million for Acthar since 2001. See id. ¶ 78.

In June 2007, Defendant “vertically integrated its sales by distributing Acthar exclusively through the specialty pharmacy CuraScript,” a subsidiary of Express Scripts. Id. ¶¶ 11, 24-25. CuraScript “is paid a fixed fee for each vial of Acthar” and has the right to return to Defendant any inventory “which goes unsold before its expiration date. Id. ¶ 76.

In 2010, Questcor established an MS Acute Exacerbation Fund (MS Fund) with Chronic Disease Fund, Inc. (CDF), a Texas-based charity. Id. ¶¶ 29, 88-89. The MS Fund helped patients with government insurance, such as Medicare, with co-pays for Acthar. Id. ¶ 89. Although the donation agreement stated that the donated funds were generally for the treatment of patients with acute exacerbations of

MS, in reality it did not provide co-pay assistance to purchase any other drugs. Id. In 2011, Questcor established a Lupus Exacerbation Fund (Lupus Fund) that was purportedly to provide co-pay assistance for “any medically appropriate therapy,” but in fact was used only to provide assistance for Acthar. Id. ¶ 91. In 2012, Questcor created a similar fund for rheumatoid arthritis (RA Fund). Id. ¶ 92. Between 2010 and 2013, Acthar sales for MS treatment nearly quadrupled. Id. ¶ 99.

Between 2013 and 2016, Questcor and then Defendant paid doctors nearly \$27.5 million purportedly for “consulting, promotional speaking, and other services related to Acthar.” Id. ¶ 107. About 35% of specialists receive payments from drug companies for similar services. Id. ¶ 106. Many of the doctors who prescribed Acthar the most were those who received substantial fees from Defendant. Id. ¶¶ 107-108.

In late 2012 and early 2013, Novartis, the company that manufactured Synacthen abroad, sought bids from companies who wanted to acquire the rights to seek FDA approval and sell Synacthen in the United States. Id. ¶¶ 65-68. Questcor and three other companies submitted serious bids. Id. The three other companies intended to develop Synacthen to compete with Acthar; Questcor had “inchoate plans for Synacthen and conducted limited due diligence when it submitted its initial offer.” Id. ¶ 68. However, Questcor’s bid was the highest, at a minimum of \$135 million. Id. ¶¶ 69-70. However, neither Questcor nor Defendant “made more than superficial efforts to pursue commercialization of Synacthen . . . to protect Acthar monopoly pricing.” Id. ¶ 73. In July 2017, the FTC approved a sublicense granting another company the rights to develop and market Synacthen in the United States. Id. ¶ 74.

II. LEGAL STANDARD

Rule 12(b)(6) allows an attack on the pleadings for failure to state a claim on which relief can be granted. “[W]hen ruling on a defendant’s motion to dismiss, a judge must accept as true all of the factual

allegations contained in the complaint.” Erickson v. Pardus, 551 U.S. 89, 94 (2007) (per curiam). However, a court is “not bound to accept as true a legal conclusion couched as a factual allegation.” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)). “Nor does a complaint suffice if it tenders ‘naked assertion[s]’ devoid of ‘further factual enhancement.’” Id. (quoting Twombly, 550 U.S. at 557) (alteration in original) (citation omitted). A complaint must “state a claim to relief that is plausible on its face.” Twombly, 550 U.S. at 570. This means that the complaint must plead “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Iqbal, 556 U.S. at 678. There must be “sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively . . . and factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation.” Starr v. Baca, 652 F.3d 1202, 1216 (9th Cir. 2011).

Ruling on a motion to dismiss will be “a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not ‘show[n]’—that the pleader is entitled to relief.” Iqbal, 556 U.S. at 679 (alteration in original) (citation omitted) (quoting Fed. R. Civ. P. 8(a)(2)).

As a general rule, leave to amend a complaint that has been dismissed should be freely granted. Fed. R. Civ. P. 15(a).

III. DISCUSSION

Plaintiff brings claims against Defendant for violations of federal and state antitrust laws, the RICO Act, state unfair competition laws, consumer fraud and deceptive trade practice laws, and insurance fraud laws, as well as tortious interference with contractual relations, and unjust enrichment.

A. Antitrust Claims (Counts One through Three)

Plaintiff alleges that Defendant has monopoly power in the market for “ACTH drugs in the United States” and that Questcor’s acquisition of the rights to develop and market Synacthen in the United States “restrained trade” in the relevant market and “eliminated [a] potential competitive threat” in order to “maintain its monopoly” so it can “stabilize or raise the price of Acthar to a higher level” than in a competitive market. FAC ¶¶ 131-133, 137-139. This conduct purportedly violates Sections 1 and 2 of the Sherman Antitrust Act and corresponding state antitrust laws.

“In order to state a Section 1 claim . . . plaintiffs must plead facts which, if true, will prove ‘(1) a contract, combination or conspiracy among two or more persons or distinct business entities; (2) by which the persons or entities intended to harm or restrain trade or commerce among the several States, or with foreign nations; (3) which actually injures competition’” and “(4) that they were harmed by the defendant’s anti-competitive contract, combination, or conspiracy, and that this harm flowed from an ‘anti-competitive aspect of the practice under scrutiny.’” Brantley v. NBC Universal, Inc., 675 F.3d 1192, 1197 (9th Cir. 2012) (first quoting Kendall v. Visa U.S.A., Inc., 518 F.3d 1042, 1046 (9th Cir. 2008); then quoting Atl. Richfield Co. v. USA Petroleum Co., 495 U.S. 328, 334 (1990)). Section 2 “targets ‘the willful acquisition or maintenance of [monopoly] power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.’” Pac. Bell Tel. Co. v. Linkline Commc’ns, Inc., 555 U.S. 438, 448 (2009) (quoting United States v. Grinnell Corp., 384 U.S. 563, 570 (1966)). “Simply possessing monopoly power and charging monopoly prices does not violate § 2.” Id. at 447-48.

Both Section 1 and Section 2 claims depend on whether Plaintiff has sufficiently alleged Defendant has market power in a relevant antitrust market. Newcal Indus., Inc. v. Ikon Office Sol., 513 F.3d 1038, 1044 n.3 (9th Cir. 2008) (“The ‘relevant market’ and ‘market power’ requirements apply identically under the two different sections of the Act, meaning that the requirements apply identically to” both

Section 1 and Section 2 claims and plaintiff's "market allegations are either sufficient or insufficient for all [antitrust] claims."). "An antitrust complaint therefore survives a Rule 12(b)(6) motion unless it is apparent from the face of the complaint that the alleged market suffers a fatal legal defect." *Id.* at 1045. One such fatal defect is the failure of the alleged market to "encompass . . . all economic substitutes for the product." *Id.*

Plaintiff alleges that the relevant market is the market for "the sale of ACTH drugs in the United States." FAC ¶¶ 131 (Section 2), 138 (Section 1). Plaintiff further alleges that Defendant's product, Acthar, "represents 100% of th[at] market." *Id.* ¶ 57. Defendant contends that this alleged market fails to include "all economic substitutes for the product," including non-ACTH drugs. Mot. at 7 (quoting *Hicks v. PGA Tour, Inc.*, 897 F.3d 1109, 1120 (9th Cir. 2018)). The Court agrees. Not only has Plaintiff failed to allege that non-ACTH drugs do not compete with ACTH drugs, but Plaintiff has specifically alleged such competition. *See, e.g.*, FAC ¶ 6 ("The advent of these safe, cheap alternative treatments in pill form reduced the need for an injectable drug derived from the pituitary gland of pigs"); *id.* ("But other than [infantile spasms] and a handful of similarly rare conditions, Acthar is . . . either a drug of last resort or not known to be clinically effective"); *id.* ¶ 13 ("doctors would not otherwise be inclined to prescribe what for most purposes is an antiquated and expensive drug that requires refrigeration and injection when cheaper, more effective pills and remedies were available"); *id.* ¶ 43 (Describing the development of "corticosteroids, a class of steroids that can also be used to fight inflammation" and "ibuprofen and certain over-the-counter NSAIDs in form that are also used to combat inflammation"); *id.* ¶ 46 ("For many of [the] conditions [for which Acthar is approved for treatment], Acthar is not considered the first-line treatment" and there "remains a lack of evidence to support the use of Acthar for most indications"); *id.* ¶ 47 ("For most indications, there is also a lack of evidence to support Acthar's use over lower-cost synthetic corticosteroids"); *id.* ¶ 49 (Acthar was "expensive to produce, difficult to apply, and (except for certain indications such as infantile spasms) not known to be more effective

than simpler, cheaper, and more widely available drugs”); id. ¶ 57 (“Acthar is priced substantially higher than non-ACTH drugs used to treat the same indications”); id. ¶ 58 (describing Sabril, “the only other FDA-approved drug for the treatment of infantile spasms”); id. ¶ 84 (“Questcor knew that it might have priced itself out of the MS market because Acthar had many cheaper, effective competitors in that market”); id. ¶ 147 (“Mallinckrodt subsidized co-pays through CDF, and paid the Prescribing Doctors, in exchange for an increased rate of prescriptions of Acthar in lieu of less expensive alternative treatment.”); id. ¶ 151 (“Mallinckrodt has asserted control over the Acthar Enterprise by issuing payments to doctors who prescribed Acthar as treatment for conditions for which more affordable alternative treatments were readily available.”).¹

The product market must include all drugs that are reasonably interchangeable. See Hicks, 897 F.3d at 1120 (“Economic substitutes have a ‘reasonable interchangeability of use’ or sufficient ‘cross-elasticity of demand’ with the relevant product”); see also Kaiser Found. v. Abbott Labs., No. CV 02-2443-JFW (FMOx), 2009 WL 3877513, at *8 (C.D. Cal. Oct. 8, 2009) (granting summary judgment where the proposed product market “excluded other alpha-blockers,” which are “reasonably interchangeable” with defendant’s drug); Bayer Schering Pharma AG v. Sandoz, Inc., 813 F. Supp. 2d 569, 577 (S.D.N.Y. 2011) (alleged product market is implausible where complaint fails to allege that “there is no combination of drugs that can serve as a functional substitute” to drugs in the proposed market). Plaintiff has failed to allege sufficiently that non-ACTH drugs are not reasonably interchangeable with ACTH drugs.²

¹ Plaintiff’s conclusory allegation that there is an “absence of competition” including a “lower-cost substitute” because of “the unavailability of Synacthen,” FAC ¶ 59, is belied by all of these other paragraphs describing a number of lower-cost substitutes.

² To the extent Plaintiff contends that lower-cost competitors are not in the relevant product market because they are not identical to Acthar, see FAC ¶ 58 (Sabril “has a different molecular structure, works differently, and is

In defense of its proposed market, Plaintiff argues that an “economic definition of a ‘market,’” rather than a “medical” one should apply. Opp’n at 6. However, Plaintiff does not explain the effect of using an “economic definition” rather than a “medical” one. Plaintiff’s citation to Morgan, Strand, Wheeler & Biggs v. Radiology, Ltd., 924 F.2d 1484 (9th Cir. 1991) does not provide any additional clarity. In Morgan, the plaintiff “contend[ed] that the relevant market [wa]s ‘referrals’ to Tucson non[-]university medical radiologists.” Id. at 1489. On summary judgment, however, the plaintiff failed to include evidence that providers of radiologists’ services outside of the definition (university radiologists, osteopathic radiologists, or non-radiologist physicians) could not compete with providers covered by the definition. Id. The Ninth Circuit held that the proposed product market was too narrow because it improperly defined the market by “the producers’ institutional associations rather than by the products’ characteristics.” Id. The court said nothing about a “medical” definition versus an “economic” one. As Defendant points out, in addressing the geographic market, as opposed to the product market, the court did note that it would “give little weight” to the doctors’ “conclusory assertion[s]” that the “relevant geographic market is Tucson” because there was “no evidence that [they] were experts qualified to opine on a highly

prescribed for a smaller set of patients than Acthar” and Rituxan, a drug used to treat severe idiopathic membranous nephropathy, “operate[s] differently than Acthar does”), it is wrong. See Hicks, 897 F.3d at 1122 (“claims of increased effectiveness” of products in the proposed submarket does not “place” those products “in a distinct market”); cf. United States v. Cont’l Can Co., 378 U.S. 441, 450, 457 (1964) (in discussing a product market for a claim under section 7 of the Clayton Act, noting that although “glass and metal containers have different characteristics which may disqualify one or the other, at least in their present form, from this or that particular use . . . interindustry competition between glass and metal containers is sufficient to warrant treating as a relevant product market the combined glass and metal container industries and all end uses for which they compete”). Plaintiff also concedes this point. See Opp’n at 6-7 n.4 (“products need not be physically identical in order to be in the same relevant market”).

technical economic question.” *Id.* at 1490. This does not mean testimony on which doctors are qualified to opine, namely, what types of drugs are used to treat certain conditions, should not be considered. Nothing in *Morgan* indicates that medical substitutes are somehow not relevant to the determination of a drug product market. In fact, it holds the contrary to be true. *Id.* at 1489 (product market insufficient where it “exclude[s] University and osteopathic radiologists’ services” without “[s]ufficient evidence for a jury to conclude that University and osteopathic radiologists cannot compete with private medical radiologists”).

To further support its argument, Plaintiff cites to a district court case denying a motion to dismiss Sherman Act claims brought against Defendant relying on the same proposed product market. Opp’n at 7 (citing *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019), *reconsideration denied*, No. 17 C 50107, 2019 WL 2763181 (N.D. Ill. May 3, 2019)). The Court is not bound to follow the conclusions reached by another district court. Further, in that case, plaintiffs alleged that “[b]y 2013, the only significant alternative to Acthar was Synacthen” and “Acthar was and continues to be the only viable product in *the market for infantile spasms and certain other conditions.*” *City of Rockford*, 360 F. Supp. 3d at 745 (emphasis added). No such allegations appear here. Moreover, the court in *City of Rockford* simply assumed that the ACTH drug market was an appropriate product market and did not undertake an analysis of whether the plaintiff’s alleged product market was facially sustainable.³

³ The FAC also refers to Defendant’s settlement with the FTC relating to its acquisition of the rights to Synacthen that required Defendant to “grant a license to develop Synacthen to treat infantile spasms and nephrotic syndrome to a licensee approved by the FTC.” FAC ¶ 74. This does not save Plaintiff’s complaint from the deficiencies in its alleged product market (and, if anything, highlights the flaws in a market definition untethered to drugs that are reasonably interchangeable for a given condition). And while “[t]he FTC settlement is not admissible to establish liability,” the FAC’s reference

Plaintiff also contends that because Defendant concedes that “[r]ather than pricing this hard-to-manufacture drug to compete with low-cost alternatives for many common types of inflammation, Questcor legitimately could choose an ‘orphan drug’ pricing strategy (one for a low-volume, high-cost drug to treat rare and catastrophic diseases) to ensure the viability of the product,” Mot. at 5, it somehow admitted Plaintiff’s market definition, Opp’n at 7. However, one does not follow from the other. Defendant merely states that it chose to raise its price and focus on “rare and catastrophic diseases” instead of “common types of inflammation.” Mot. at 5. This says nothing about an ACTH market or reasonable substitutes for Acthar.

Plaintiff next contends that “there is nothing inconsistent or implausible about Acthar competing in more than one kind of market.” Opp’n at 7. This is certainly true and is undisputed by Defendant. See Reply at 3. But that there is a broad market for drugs, and submarkets for certain indications, does not establish a product market for ACTH drugs.⁴ “To plead an antitrust claim based on a submarket, ‘the

to it is not a “redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). Defendant’s motion to strike, Mot. at 2, 10, is DENIED.

⁴ The FTC amicus curiae brief cited by Plaintiff, Opp’n at 7, does not compel a different conclusion. In the FTC’s brief, it argued that “when multiple types of anticompetitive harm are alleged (as here), multiple [product] markets may be relevant.” Staley v. Gilead Sciences, Inc., No. 3:19-cv-02573-EMC (N.D. Cal.), Dkt. 180-1 at 2. Specifically, because the complaint alleged two types of harm (preventing competition from generics and reducing competition among branded HIV medications), “the case may implicate multiple relevant markets.” Id. at 1, 10. However, the FTC did not take a “position on whether the complaint contain[ed] sufficient facts supporting the alleged product markets.” Id. at 11. It merely noted that the fact that products “compete[] to some degree in broader spheres as well . . . d[oes] not preclude defining more narrow relevant antitrust markets when assessing the specific alleged anticompetitive effects at issue.” Id. at 5. For example, the FTC noted that “the relevant market might consist of an entire therapeutic class of drugs when the anticompetitive effects are likely to manifest among that entire class, such as in a merger between two branded

plaintiff must be able to show (but need not necessarily establish in the complaint) that the alleged submarket is economically distinct from the general product market.” Hicks, 897 F.3d at 1121. A plaintiff can do so by alleging “industry or public recognition of the submarket as a separate economic entity, the product’s peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors.” Id. (quoting Brown Shoe Co. v. United States, 370 U.S. 294, 325 (1962)). Here, the FAC contains no allegations tending to show these factors indicate an ACTH submarket, with the possible exception of distinct prices. And to the contrary, as explained above, the FAC contains allegations tending to show that other drugs have similar characteristics (e.g., anti-inflammation), similar uses (e.g., MS, Lupus, rheumatoid arthritis), similar customers (e.g., Medicare recipients with certain conditions), and even sensitivity to price change (i.e. the purported impetus for the alleged bribes and co-pay funds), see FAC ¶ 96 (“Questcor conducted research and discovered that price was an obstacle to more prescriptions . . .”). Therefore, Plaintiff’s antitrust claims fail not because Acthar cannot be a participant in multiple markets (it can), but because Plaintiff has failed to plead sufficient facts to support an ACTH market in particular.

Plaintiff additionally argues that Defendant was able to raise its prices exponentially “without losing sales [t]o corticosteroids or any other non-ACTH drug.” Opp’n at 6 (citing FAC ¶¶ 2, 8, 51–55, 72). However, none of those cited paragraphs contains allegations supporting such a claim. That “Acthar net sales increased,” “Medicare spending on Acthar increased,” and “the number of Medicare Part D claims” increased, see id. ¶¶ 54–55, does not show that Defendant did

manufacturers,” while “[i]n other circumstances, the relevant market might be limited to only a subset of a therapeutic class” or even to “the brand and generic versions of that product.” Id. at 8–9. However, that a more specific market might exist does not mean that any proposed “submarket” is sufficient. A complaint must still “plead sufficient facts to support [the] alleged relevant markets.” See id. at 10. Plaintiff has failed to do so here.

not lose sales to its competitors. Further, the largest increase (1300%) occurred in 2007, see id. ¶ 52, years before Defendant acquired the rights to Synacthen and before Acthar was approved for infantile spasms, the indication for which it is the first-line treatment. And importantly, Plaintiff alleges that its sales increased in large part during the relevant time period because of Defendant's illegal actions to increase demand, not because of its market power in the ACTH market. See, e.g., FAC ¶ 99 (The co-pay funds "worked as planned" as "MS sales nearly quadrupled between the third quarter of 2010 (when Questcor established the MS 'acute exacerbation' fund) and the third quarter of 2013."); id. ¶ 104 ("Mallinckrodt's co-pay subsidies were one way to prop up demand and receive payment from third-party payors such as Humana."); id. ¶ 105 ("In the several decades prior [to 2014], Acthar had not been prescribed in large quantities for these conditions [rheumatology, pulmonology, ophthalmology, dermatology, and kidney disease] despite having been FDA approved for such treatments."); id. ¶ 108 ("In order to increase the prescription rates of Acthar, the Prescribing Doctors would need to prescribe Acthar in situations in which it was not called for and in lieu of considerably more cost-effective medications."); id. ¶ 147 ("Mallinckrodt subsidized co-pays through CDF, and paid the Prescribing Doctors, in exchange for an increased rate of prescriptions of Acthar in lieu of less expensive alternative treatment.").

Perhaps acknowledging the weakness in its product market definition, Plaintiff asserts that it can alternatively show direct proof of market power. Opp'n at 6. However, Plaintiff's allegations on this point also fail. "Direct proof of market power may be shown by evidence of restricted output and supracompetitive prices." Forsyth v. Humana, Inc., 114 F.3d 1467, 1475 (9th Cir. 1997), aff'd, 525 U.S. 299 (1999), and overruled on other grounds by Lacey v. Maricopa Cty., 693 F.3d 896 (9th Cir. 2012). Plaintiff has certainly alleged that Defendant charges supracompetitive prices. FAC ¶¶ 2-3, 8, 47, 51-53, 58. But, it fails to allege Defendant restricted output. Forsyth, 114 F.3d at 1476 (plaintiffs "failed to present direct evidence of market power" where they "submitted evidence that [defendant] routinely charged higher

prices than other hospitals while reaping high profits” but failed to make a “showing of restricted output”); cf. Rebel Oil Co. v. Atl. Richfield Co., 51 F.3d 1421, 1436 (9th Cir. 1995) (the existence of a price differential or prices that are not closely correlated is insufficient, by itself, to exclude products from a market). To the contrary, Plaintiff has alleged that “the number of Medicare Part D claims for Acthar has grown by more than 700% from 2011 to 2016.” FAC ¶ 55.

Because the Court finds Plaintiff has failed to allege a facially sustainable product market definition, or sufficiently allege direct proof of market power, the Court does not address Defendant’s arguments about antitrust injury.

The First through Third Counts are DISMISSED with leave to amend.

B. RICO (Counts Four and Five)

To state a RICO claim, a plaintiff must allege “(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity.” Odom v. Microsoft Corp., 486 F.3d 541, 547 (9th Cir. 2007) (quoting Sedima, S.P.R.L. v. Imrex Co., 473 U.S. 479, 496 (1985)). “[T]he conduct must be (5) the proximate cause of harm to the victim.” Eclectic Properties E., LLC v. Marcus & Millichap Co., 751 F.3d 990, 997 (9th Cir. 2014). Racketeering activity “encompass dozens of state and federal offenses, known in RICO parlance as predicates.” RJR Nabisco, Inc. v. European Cmty., 136 S. Ct. 2090, 2096 (2016). There is a pattern of racketeering activity where there is “a series of related predicates that together demonstrate the existence or threat of continued criminal activity.” Id. at 2096-97. “[F]ailure to adequately plead a substantive violation of RICO precludes a claim for conspiracy.” Howard v. Am. Online Inc., 208 F.3d 741, 751 (9th Cir. 2000).

Plaintiff alleges the “Acthar Enterprise,” consisting of Defendant, Express Scripts (and its subsidiaries), CDF, and the prescribing doctors, was “used as a tool to effectuate a pattern of racketeering activity.” FAC ¶ 146. Specifically, Defendant 1) made allegedly false statements, including that Defendant was in compliance with the laws,

which constituted mail and wire fraud, as well as use of interstate facilities to conduct unlawful activity, and 2) subsidized co-pays through CDF and made payments to the prescribing doctors which “violated state commercial bribery statutes.” *Id.* ¶¶ 147-49, 153.

1. Conduct of an Enterprise

Plaintiff alleges that the Acthar Enterprise is an association-in-fact enterprise that was ongoing and functioned as a continuing unit. FAC ¶ 146. “[A]n associated-in-fact enterprise is ‘a group of persons associated together for a common purpose of engaging in a course of conduct.’” *Odom*, 486 F.3d at 552 (citing *United States v. Turkette*, 452 U.S. 576, 583 (1981)). “To establish the existence of such an enterprise, a plaintiff must provide both ‘evidence of an ongoing organization, formal or informal,’ and ‘evidence that the various associates function as a continuing unit.’” *Id.* (citing *Turkette*, 452 U.S. at 583). Defendant only challenges whether Plaintiff sufficiently alleged a common purpose. *See* Mot. at 20-22.

Plaintiff alleges that “Mallinckrodt designed and coordinated” the Acthar Enterprise for the purpose of “charg[ing] and maintain[ing] inflated prices for Acthar.” FAC ¶ 83; *see also id.* ¶ 147 (Defendant “established the Acthar Enterprise to fraudulently increase its sales of Acthar”). Plaintiff also alleges that “[t]he purpose and effect of the conspiracy was to induce sales of Acthar that otherwise would not have been made in the absence of the illegal conduct and to maintain or raise the price of Acthar to a higher level than it would have commanded in the absence of the illegal conduct.” *Id.* ¶ 165.⁵ Defendant contends

⁵ In opposition, Plaintiff argues that the Acthar Enterprise acts “for the common purpose of defrauding payors for their own financial benefit.” Opp’n at 11 (citing FAC ¶ 146). That paragraph of the FAC states only that “[t]he Acthar Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity,” it does not state a common purpose of defrauding payors for their own financial benefit. Nevertheless, that asserted common purpose is apparent from the allegations in the FAC, even if not alleged in those exact words.

that Plaintiff has not pleaded “any facts plausibly suggesting that” anyone other than Defendant “shared such purposes,” and to the contrary Plaintiff alleged that CuraScript received a “fixed fee for each vial of Acthar” and therefore would not have an incentive to raise Acthar’s price. Mot. at 20. Defendant’s argument is not convincing.

Plaintiff has plausibly alleged the conduct of an enterprise based on Ninth Circuit law as set out in Odom and River City Markets, Inc. v. Fleming Foods W., Inc., 960 F.2d 1458 (9th Cir. 1992). In Odom, plaintiff brought RICO claims against Microsoft and Best Buy based on an agreement between them where Microsoft invested in, and promoted, Best Buy and Best Buy promoted Microsoft’s MSN internet access service and other Microsoft products. 486 F.3d at 543. Plaintiff alleged that when a customer purchased a laptop or phone from Best Buy, Best Buy would provide the customer with an MSN trial CD and would pass the customer’s credit card information to Microsoft, which would bill the person for MSN if he did not cancel the trial. Id. The Ninth Circuit held that the complaint sufficiently alleged a common purpose of “increasing the number of people using [MSN], and doing so by fraudulent means.” Id. at 552. Similarly here, Plaintiff has alleged a common purpose of increasing the number of people using Acthar, and doing so by fraudulent means, including allegedly illegal bribes and co-pay subsidies. Further, the Ninth Circuit in Odom found there was still a common purpose even though Best Buy did not directly benefit from the improper billing for MSN—there were no allegations that Best Buy received a kickback. Here, while the CDF may not directly receive a kickback from the scheme, the CDF presumably benefits indirectly through Defendant’s donations and referrals, which are alleged to be tied directly to Defendant’s need to “confirm the amount of future payments to CDF necessary to keep paying Acthar co-pay subsidies smoothly.” FAC ¶ 98.

In River City, plaintiffs brought RICO claims against a grocery store chain for engaging in “a fraudulent scheme to unload unprofitable properties on unsuspecting purchasers.” 960 F.2d at 1459. Plaintiffs had alleged that the defendants “jointly induced the plaintiffs to purchase certain [grocery] stores” and then one defendant (Alpha Beta)

“destroyed the business value of the stores” between “the acceptance of plaintiffs’ bids and the transfer of the stores.” Id. at 1460. The Ninth Circuit found these allegations sufficient to survive a motion to dismiss. Id. However, the Circuit also considered whether the plaintiffs’ claims could survive summary judgment and found they could not. Id. at 1463. There was simply no evidence that “the agreement . . . would, if carried out according to its terms, violate any federally protected rights of the plaintiffs” or any “evidence of any contemplated overreaching, deceit, nondisclosure, manipulation of inventory, or any other unethical conduct.” Id. at 1463. While there was evidence of Alpha Beta’s wrongdoing, there was a lack of evidence as to the other defendant, Fleming. Id. at 1464. The evidence showed that, at most, Fleming knew about Alpha Beta’s alleged wrongdoing for no more than a month—an insufficient length of time to establish a pattern of racketeering activity. Id. The Ninth Circuit did not address the “conduct of the enterprise” element in its summary judgment discussion. Regardless, here, unlike in River City, Plaintiff alleges facts supporting that at least CDF and the allegedly bribed doctors were aware of the allegedly fraudulent scheme. See FAC ¶¶ 89, 91, 98, 108, 147, 151.

Defendant contends that “numerous district courts in the Ninth Circuit have dismissed RICO claims that are, like those asserted by Humana here, based on (a) alleged associations in fact among entities with business relationships, and (b) alleged racketeering activity advancing only the particular interests of one member of the alleged associations.” Mot. at 20 & n.9. However, the cases cited by Defendant are distinguishable. For example, in Woodell v. Expedia Inc., No. C19-0051JLR, 2019 WL 3287896 (W.D. Wash. July 22, 2019), plaintiff alleged that Expedia (and its subsidiaries) and Reservations.com had the common purpose of “obtaining tax overpayments from consumers.” Id. at *7. However, the Court found that while the complaint alleged Expedia improperly charged “Taxes & Fees” that covered more than money owed to the government on Reservations.com’s website, there were “no specific factual allegations that any other Defendant acted with an objective unrelated to ordinary business aims.” Id. To the

contrary, the plaintiff had conceded that Reservations.com was “not involved in the collection of the . . . charge at issue . . . or the remission process,” and had not alleged “any communication, meeting, agreement, or moment in time when Defendants and Reservations.com agreed to coordinate regarding representations about the ‘Taxes & Fees’ charge that appears on the Reservations.com website.” *Id.* at *2, *3. The only allegation tying Reservations.com to the alleged conduct of the enterprise was that, on information and belief, Reservations.com was a knowing and willing participant. *Id.* at *2. Here, there is more than a conclusory allegation as to the other parties’ involvement in, and knowledge of, the alleged fraud. There are specific allegations that CDF and the prescribing doctors acted in ways unrelated to ordinary business aims. As Plaintiff points out, CDF knowingly established co-pay subsidy funds outside of its normal programs solely funded by Defendant and solely used to pay patients who are prescribed Defendant’s drug, and the doctors accepted bribes. *Opp’n* at 12.⁶

⁶ In each of the other cases, the other alleged members of the enterprise were unaware of the defendant’s (or other alleged enterprise member’s) fraudulent activity. *See, e.g., Gomez v. Guthy-Renker, LLC*, No. EDCV 14-01425 JGB (KKx), 2015 WL 4270042, at *2, *5, *11 (C.D. Cal. July 13, 2015) (dismissing RICO claim for failing to adequately allege an enterprise between an allegedly fraudulent sales business and the payment processors and customer service companies the business utilized, where there was no evidence that anyone other than defendant was aware of the alleged fraud); *Hilton v. Apple Inc.*, No. CV 13-7674 GAF (AJWx), 2014 WL 12597143, at *8 (C.D. Cal. Jan. 9, 2014) (dismissing RICO claim for failing to adequately allege an enterprise between Apple and AT&T where plaintiff alleged nothing more than “a garden variety, run-of-the-mill business relationship, along with Apple’s allegedly undisclosed decision to commit fraud.”); *Missaghi v. Apple Inc.*, No. CV 13-02003 GAF (AJWx), 2013 WL 12200086, at *7 (C.D. Cal. Nov. 1, 2013) (same); *In re Countrywide Fin. Corp. Mortg.-Backed Sec. Litig.*, No. 2:11-CV-07166-MRP, 2012 WL 10731957, at *8 (C.D. Cal. June 29, 2012) (dismissing a claim under the Ohio Corrupt Activities Act (Ohio’s RICO analogue) for failing to allege an enterprise between the defendant and third parties who provided the defendant with services where plaintiff pleaded no facts that the purpose of those business relationships was to profit illegally); *In re Jamster*

Defendant also cites United Food & Commercial Workers Unions & Employers Midwest Health Benefits Fund v. Walgreen Co., 719 F.3d 849 (7th Cir. 2013). Plaintiff contends that this case “improperly narrows Ninth Circuit law” and therefore the standard set in that case “does not apply. See Opp’n at 12. Even if the Court were to follow Walgreen, it is distinguishable from this case. In Walgreen, the Seventh Circuit held that conduct of an enterprise had not been sufficiently alleged where the complaint did not include allegations that “officials from either company involved themselves in the affairs of the other” or that “profits from the illegal drug-switching scheme were siphoned off to the . . . enterprise or to individual enterprise members.” 719 F.3d at 854-55. The complaint had alleged only that the drug manufacturer and the pharmacy communicated, and that the pharmacy implemented an “illegal dosage-form-switching program using [the drug manufacturer’s] pills.” Id. at 854. However, the Seventh Circuit noted that “[a] corporation, after all, is perfectly capable of breaking the law on its own behalf. The complaint describes conduct that might plausibly state a claim for fraud (among other things) against either defendant, but RICO does not penalize parallel, uncoordinated fraud.” Id. at 855.

Here, as for the doctors, the alleged bribes clearly fall outside of a legitimate commercial relationship. See id. at 855 (That the pharmacy “purchased its generic [drugs] from [the manufacturer] . . . shows only that the defendants had a commercial relationship”). And unlike in Walgreen, Plaintiff has alleged that Defendant was very involved in the operations of CDF. For example, Plaintiff alleges that “[t]hough CDF already had a fund for MS patients . . . Questcor and CDF established a

Mktg. Litig., No. 05CV0819 JM (CAB), 2009 WL 1456632, at *5-*7 (S.D. Cal. May 22, 2009) (dismissing RICO claim for failing to allege an enterprise between wireless providers and companies that sell ring tones and wallpapers (content providers), where the wireless providers made money from content sales, but there were no allegations that the wireless provides were in any way involved in the content providers’ allegedly deceptive advertising).

new ‘MS Acute Exacerbation Fund’ just for patients with government insurance . . . and just for the co-pays of Acthar but no other drugs,” funded entirely by Defendant. FAC ¶¶ 88-89. In addition, Plaintiff alleged that Questcor “sent patients to CDF through Questcor’s ‘reimbursement hub’ for Acthar,” called the ASAP program, and that “[t]he ASAP program referred over 98 percent of the patients who received co-pay subsidies from the . . . funds at CDF. *Id.* ¶¶ 90, 93. CDF was also involved in the operations of Defendant in that it established three funds at Defendant’s direction to subsidize co-pays for Defendant’s drug, and provided “detailed financial reports” to Defendant “containing information about how many patients were enrolled in the fund, how much the fund had already paid out, and how much had been allocated to enrolled patients,” as well as “the percentage of patients approved to receive co-pay subsidies, the average co-pay amount paid by the fund, the total number of resulting drug ‘dispenses’ (broken out by new dispenses vs. refills), and the remaining fund balance.” *Id.* ¶¶ 88-92, 98.

Plaintiff has sufficiently alleged conduct of the Acthar Enterprise.

2. Pattern of Racketeering Activity

a. Mail and Wire Fraud

“The mail and wire fraud statutes are identical except for the particular method used to disseminate the fraud, and contain three elements: (A) the formation of a scheme to defraud, (B) the use of the mails or wires in furtherance of that scheme, and (C) the specific intent to defraud.” *Eclectic Properties*, 751 F.3d at 997 (citing *Schreiber*, 806 F.2d at 1400).

Where RICO predicates are fraud based, allegations must comply with Federal Rule of Civil Procedure 9(b), which requires that circumstances constituting fraud be stated with particularity. *Alan Neuman Prods., Inc. v. Albright*, 862 F.2d 1388, 1392 (9th Cir. 1988) (Where RICO claim is based on mail and wire fraud, Rule 9(b) “requires that circumstances constituting fraud be stated with particularity”; complaint is fatally flawed when “[t]he allegations of predicate acts in

the complaint concerning those elements of RICO are entirely general; no specifics of time, place, or nature of the alleged communications are pleaded.”). However, “[t]he only aspects of wire fraud that require particularized allegations are the factual circumstances of the fraud itself.” Odom, 486 F.3d at 554. Because “the formation of a scheme or artifice to defraud” and the “specific intent to deceive or defraud” require “a showing of the defendants’ state of mind, general rather than particularized allegations are sufficient.” Id.

Compliance with State and Federal Law. Plaintiff alleges that Defendant “directly misrepresented to [Plaintiff] that it was complying with state and federal law, including laws related to bribery, kickbacks, and false claims” when Defendant (and CuraScript) submitted data for Prescription Drug Event (PDE) claims “certifying that such data is true, accurate, and complete.” FAC ¶¶ 111-116. Defendant notes that Plaintiff “does not allege that [Defendant] denied to [Plaintiff] that they had made contributions to CDF’s co-pay assistance funds, nor misrepresented to [Plaintiff] the details of those funds,”⁷ but allegedly misrepresented that they were complying with the law because the co-pay assistance programs violated federal statutes, including the Anti-Kickback Statute (AKS) and the False Claims Act (FCA). Mot. at 13.

First, Defendant asserts in conclusory fashion that “[t]his allegation lacks sufficient particularity to satisfy Rule 9(b).” Mot at 13. Plaintiff has alleged that each time Defendant certified that it was in compliance with federal and state laws, it knowingly made a false

⁷ The Court notes that the FAC could be read to make such a claim. See FAC ¶ 89 (“Questcor’s donation agreement [for the MS Fund] falsely represented that the funds were generally for treatment of patients with acute exacerbations of MS, when in fact Questcor knew it was just for patients using Acthar.”), ¶ 91 (The Lupus Fund agreement “falsely stated that the fund was for ‘any medically appropriate therapy,’ when in fact Questcor intended to fund only Acthar and exclude other therapies.”). However, Plaintiff does not allege that it actually saw the donation agreements at any point in time.

statement because it knew at the time it made the statements that its co-pay assistance violated federal statutes and its doctor payments violated state law. This is sufficient.

Next, Defendant contends that Plaintiff has failed to allege fraudulent intent because “the OIG had issued guidance expressly endorsing patient assistance programs for Medicare Part D enrollees, including pharmaceutical manufacturer funding of such programs.” Mot. at 13.⁸ However, this misstates the Court’s inquiry on a motion to dismiss. It need not determine whether Defendant in fact had a fraudulent intent. Rather, it must only determine whether Plaintiff has plausibly alleged a fraudulent intent with general allegations. Plaintiff has done so. See FAC ¶¶ 101 (“The Company’s knowledge and willfulness is evidenced by internal training materials that instructed its employees on these laws and their relevant prohibitions; corporate policies reflecting the Company’s knowledge of its illegality; trade publications and articles circulated among the key executives and consultants warning against the practice; and longstanding and repeated warnings about the practice from the Office of the Inspector General of the United States Department of Health and Human Services.”), 147 (Defendant “established the Acthar Enterprise to fraudulently increase its sales of Acthar” by making payments “in exchange for an increased rate of prescriptions of Acthar in lieu of less expensive alternative treatment” and “Mallinckrodt, CDF, and the Prescribing Doctors knew that their scheme violated federal and state laws.”).

Even were the Court to consider the 2005 OIG SAB, that guidance does not support Defendant’s position that it could not have acted with fraudulent intent “as a matter of law” because it “had a good-faith basis to certify compliance in light of OIG guidance that

⁸ Pursuant to Federal Rule of Evidence 201(b), the Court GRANTS Defendant’s unopposed request for judicial notice (RJN) of the 2005 and 2014 OIG Special Advisory Bulletins. Dkt. 48 (RJN), Exs. A (2005 SAB), K (2014 SAB).

continued in effect until 2014.” Reply at 5; see also Mot. at 15 (“[T]he OIG’s guidance indisputably establishes a good faith basis for a general representation of compliance with law”). Specifically, the 2005 SAB provides that “pharmaceutical manufacturer PAPs [patient assistance programs] that subsidize Part D cost-sharing amounts present heightened risks under the antikickback statute,” but “cost-sharing subsidies provided by bona fide, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions.” RJN, Ex. A at 8. However, the OIG “would not consider a charitable foundation (or similar entity) formed, funded or controlled by a manufacturer . . . to be a bona fide, independent charity, because . . . the foundation would receive all of its funding from the pharmaceutical manufacturer (or its affiliates) and would provide subsidies only for the manufacturer’s products.” Id. at 8 n.3. Similarly, the 2005 SAB notes that subsidies provided by a drug manufacturer for the manufacturer’s product “would implicate the antikickback statute and pose a substantial risk of program and patient fraud and abuse” and “would be squarely prohibited by the statute.” Id. at 9. Here, Plaintiff alleges that the CDF funds at issue were “exacerbation funds” for diseases that the CDF’s other funds already covered, that these funds received all of their funding from Defendant and provided subsidies only for Acthar, and that the CDF provided data to Acthar about the subsidies that were paid. FAC ¶¶ 88-98; see also Opp’n at 15. Therefore, the Court rejects Defendant’s contention. Accepting the FAC’s allegations as true, it is more than plausible that Defendant acted with fraudulent intent in certifying that the co-pay assistance funds complied with federal law.⁹

⁹ That the 2014 SAB was purportedly stricter does not change the import of the clear language in the 2005 SAB. Neither does the Court find the OIG advisory opinions, RJN, Exs. B-I, J, were it appropriate to consider them, convincing. See United States ex rel. Strunck v. Mallinckrodt Ard LLC, No. CV 12-175, 2020 WL 362717, at *6 (E.D. Pa. Jan. 22, 2020) (denying Mallinckrodt’s motion to dismiss based on similar arguments, specifically rejecting proposed implication from footnote in OIG guidance and advisory

Third, Defendant argues that any racketeering acts related to the co-pay assistance funds occurred outside the four-year statute of limitations.¹⁰ Mot. at 16. Plaintiff alleges that Defendant “marketed guaranteed co-pay assistance to physicians and patients . . . throughout the relevant time period,” that “through 2014, the Lupus Exacerbation fund paid the co-pays of Acthar but no other drug,” and that “[o]n information and belief, Mallinckrodt continued to pay or substantially subsidize required patient co-payments for Acthar after 2014 and continues to do so until today.” FAC ¶¶ 91, 95, 102 (citing Defendant’s website). Plaintiff further alleges that it “could not have discovered and remained unaware of the foregoing conduct until the Federal Trade Commission and the United States Department of Justice brought these acts and practices to light through investigations, legal actions, and/or settlements.” Id. ¶ 123.

The Ninth Circuit “follow[s] the ‘injury discovery’ statute of limitations rule for civil RICO claims.” Pincay v. Andrews, 238 F.3d 1106, 1109 (9th Cir. 2001). In other words, the statute begins running when plaintiff has either actual or constructive notice. Id. Defendant argues that Plaintiff “had constructive notice of its injury when patients used the program to meet a co-pay for a prescription that Humana covered” because of “the publicized nature of the co-pay assistance program.” Mot. at 16 n.5. It is not alleged in the FAC that Plaintiff was in any way notified whether co-pays were subsidized by

opinion that there are “rare circumstances” where there may be only one drug covered by Medicare for a particular disease). Importantly, as Plaintiff notes, Opp’n at 15-16, MS, RA, and Lupus, the conditions for which Defendant established co-pay funds, have other drugs that are the “first-line” treatment and therefore the “rare circumstance” where only one drug is approved for certain diseases does not apply in any event.

¹⁰ Defendant’s related argument that Plaintiff “makes no factual allegations that the challenged conduct continued after the OIG revised its guidance regarding patient assistance programs in 2014,” Mot. at 16, is not relevant to resolution of this motion for the reasons discussed in the preceding paragraph.

assistance funds. In fact, Plaintiff's allegations about its members indicate otherwise. See FAC ¶ 120 ("Humana members are required to pay what they owe for drug coverage under Medicare Part D and other kinds of plans Through its illegal scheme to pay patient co-pays through phony charitable funds at CDF, Mallinckrodt caused Humana members to unintentionally misrepresent that they had paid their contractual share of prescription drug coverage"). The mere receipt or payment of claims, when there is "no reason to think that Plaintiff knew those [claims] were fraudulent or excessive when it paid them," does not establish constructive knowledge of Plaintiff's injury. State Comp. Ins. Fund v. Capen, No. SACV 15-1279 AG (CWx), 2015 WL 13298073, at *5 (C.D. Cal. Dec. 18, 2015).

Nor is there anything in the FAC that indicates the allegedly illegal aspects of Defendant's co-pay assistance program were widely publicized, or that the information to be gleaned from the purported publicity could be imputed to Plaintiff. See Living Designs, Inc. v. E.I. Dupont de Nemours & Co., 431 F.3d 353, 365 (9th Cir. 2005) ("[T]he district court erred in determining that, as a matter of law, the attention received by [a sanction order against defendants] could be imputed to the Plaintiffs"). Although the FAC alleges that Defendant "marketed guaranteed co-pay assistance to ***physicians and patients*** as a way to neutralize concerns about the price and to induce sales and Medicare reimbursement," FAC ¶ 95 (emphasis added), nothing in the FAC supports the conclusion that this marketing put the doctors or patients on notice of the allegedly illegal aspects of those funds, or that insurance providers (who were not recipients on this advertising) would somehow know about the illegal aspects. For example, there is no allegation to support the fact that it was publicized that Defendant was even a donor to those funds, let alone the exclusive owner that referred nearly 100% of the patients to the fund or that the funds only covered Acthar. Further, Plaintiff has alleged that the donation agreements fraudulently misrepresented that the funds were not limited to patients using Acthar. FAC ¶¶ 89, 91. Therefore, had Plaintiff inquired into the funds, it would not have discovered that the funds were illegal. Cf. Living Designs, 431 F.3d at 365 (plaintiff has constructive notice where

“an investigation which, if reasonably diligent, would have led to discovery of the fraud”).

Therefore, Plaintiff’s allegation that it did not, and could not have, discovered its injury until the “United States Department of Justice brought these acts and practices to light through investigations, legal actions, and/or settlements,” FAC ¶ 123, is plausible. Because the DOJ press release announcing it filed a complaint against Defendant for its conduct related to the co-pay assistance funds was published on June 5, 2019,¹¹ Plaintiff brought these claims well within the four-year limitations period.¹²

Finally, Defendant contends that because the AKS and FCA are not predicate acts, wire fraud and mail fraud based on alleged violations of those statutes should not result in RICO liability. Mot. at 16. However, unlike the cases cited by Defendant,¹³ it is not the

¹¹ The Court takes judicial notice of the date of the DOJ press release available at <https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-drug-maker-mallinckrodt-alleging>. Fed. R. Evid. 201(b); Daniels-Hall v. Nat’l Educ. Ass’n, 629 F.3d 992, 998-99 (9th Cir. 2010) (The Court may “take judicial notice of [] information . . . made publicly available by government entities” whose accuracy is not disputed by the parties.”); Taleff v. Sw. Airlines Co., 554 F. App’x 598, 599 (9th Cir. 2014) (taking judicial notice of a Department of Justice press release).

¹² The Court therefore need not address the issue of fraudulent concealment.

¹³ See Ayres v. Gen. Motors Corp., 234 F.3d 514, 521 (11th Cir. 2000) (“Plaintiffs have identified no affirmative misrepresentation on the part of the Defendants” and rely solely on a duty to disclose under the National Traffic and Motor Vehicle Safety Act); Danielsen v. Burnside-Ott Aviation Training Ctr., Inc., 941 F.2d 1220, 1229 (D.C. Cir. 1991) (Plaintiff alleged only that Defendant violated the Service Contract Act, but a violation of that act “fall[s] short” of a “scheme or artifice to defraud”); Norman v. Niagara Mohawk Power Corp., 873 F.2d 634, 636 (2d Cir. 1989) (RICO allegations that defendant retaliated against plaintiff was essentially a whistleblower complaint that must be brought before the Secretary of Labor); Butchers’ Union, Local No. 498, United Food & Commercial Workers v. SDC Inv., Inc.,

violation of the AKS or the FCA itself that is alleged to form the basis for the wire and mail fraud, but the false certifications to Plaintiff about compliance with those statutes. See Opp'n at 17.

Doctor Misrepresentations. Plaintiff alleges that when the doctors who prescribed Acthar got prior authorization from Plaintiff, they falsely represented that “the prescription medication is medically necessary, up-to-date, and non-duplicative” and “that they are not violating state or federal law applicable to the provision of their services” because they had accepted money in exchange for those prescriptions.” FAC ¶¶ 117-118. Defendant does not address this type of misrepresentation separately. However, for the reasons stated above, Plaintiff has sufficiently alleged that such statements are predicate RICO acts of the Acthar Enterprise.

Insured Misrepresentations. Plaintiff also alleges that Defendant caused patients to “unintentionally misrepresent that they had paid their contractual share of prescription drug coverage” when in fact their co-pays were paid by “phony charitable funds at CDF.” FAC ¶ 120. However, Plaintiff has failed to allege how a representation by patients that they paid their co-pays is rendered false merely because they received the funding from a co-pay assistance program. The 2005 SAB specifically contemplates this scenario. RJN, Ex. A at 9 (“[C]ost-sharing assistance furnished by a PAP, including a manufacturer PAP, will count toward a beneficiary’s [true out-of-pocket] expenditures, even if the PAP does not comply with the fraud and abuse laws.”).

631 F. Supp. 1001, 1010 (E.D. Cal. 1986) (any claim that is “arguably within the [Labor] Board’s jurisdiction . . . is preempted” and therefore any RICO claim based on conduct that “otherwise falls within the exclusive jurisdiction [of] the NLRB” will be preempted); see also Bodimetric Health Servs., Inc. v. Aetna Life & Cas., 903 F.2d 480, 488 n.7 (7th Cir. 1990) (plaintiff had withdrawn the civil RICO count for jurisdictional purposes).

Therefore, Plaintiff has failed to plead mail or wire fraud based on this conduct.

b. Bribery

Co-pay Assistance. Defendant contends that co-pay assistance is not a bribe under the relevant state laws because it was not given to 1) an “employee to induce the employee to use his or her employment for the benefit of the person,” or 2) a physician to induce a breach of the physician’s duty to a patient.” Mot. at 12 n.4 (citing the California and Alaska bribery statutes as examples). Plaintiff contends that bribery also applies to “the acceptance of ‘compensation or inducement’ for referral of patients . . . by those processing or presenting insurance claims.” Opp’n at 17 (citing Cal. Ins. Code § 750).

The Travel Act prohibits, among other things, use of interstate commerce to conduct “unlawful activity.” Unlawful activity includes “bribery . . . in violation of the laws of the State in which committed.” 18 U.S.C. § 1952(b)(2). The Supreme Court has interpreted “bribery” in this statute to mean “the generic definition of bribery, rather than a narrow common-law definition.” Perrin v. United States, 444 U.S. 37, 49 (1979). Therefore, “the Travel Act [] encompass[es] conduct in violation of state commercial bribery statutes.” Id. at 50. Other courts in this district have interpreted this to include statutes prohibiting bribery-like conduct, whether or not the statute is identified as a bribery statute. See, e.g., United States v. Rogers, 389 F. Supp. 3d 774, 787 (C.D. Cal. 2019) (California Insurance Code Section 750 prohibits bribery, as that term is used in the Travel Act); United States v. Gross, 370 F. Supp. 3d 1139, 1149 (C.D. Cal. 2019) (same); cf. United States v. Nardello, 393 U.S. 286, 295 (1969) (“[T]he inquiry [under the Travel Act] is not the manner in which States classify their criminal prohibitions but whether the particular State involved prohibits the extortionate activity charged.”). This Court finds the analysis in those cases to be convincing. A violation of California Insurance Code Section 750 constitutes bribery under the Travel Act.

However, the FAC fails to allege how Section 750 was violated. That statute prohibits “any person . . . who engages in the practice of processing, presenting, or negotiating claims, including claims under policies of insurance” from “offer[ing], deliver[ing], receiv[ing], or accept[ing] any . . . consideration . . . as compensation or inducement to or from any person for the referral or procurement of clients, cases, patients, or customers.” Cal. Ins. Code § 750(a). Plaintiff does not allege which relevant party purportedly “engages in the practice of” presenting insurance claims and accepted money in exchange for the referral of patients. The only parties that receive consideration as part of the co-pay funds are CDF and the patients. Plaintiff does not allege that CDF engages in the practice of presenting insurance claims, nor is it clear that this statute applies to patients themselves. Therefore, Plaintiff has not sufficiently alleged that the co-pay assistance funds constituted bribery.

Bribes to Doctors. Defendant also contends that Plaintiff has failed to allege more than “conclusory contentions” showing the payments to doctors were for an unlawful, rather than lawful, purpose. See Mot. at 17-19. The Court disagrees. Plaintiff’s allegations go beyond the evidence of correlation identified in the journal article in paragraph 106 of the FAC. Plaintiff also alleges that 1) in 2007, Defendant “knew that it might have priced itself out of the MS market,” 2) Defendant “heavily marketed” Acthar to doctors who treated conditions such as MS, rheumatoid arthritis, and sarcoidosis, 3) “Acthar had not been prescribed in large quantities for these conditions” prior to 2014, 4) in 2014, the president of the business selling Acthar told investors about “a strategy to expand Acthar’s sales to patients” with these and other conditions even though “there were no new medical studies suggesting Acthar was needed to treat any of these conditions,” 5) today, “fewer than 10% of Acthar’s sales come from prescriptions for infantile spasms,” and 6) 88% of doctors who submitted more than 10 Medicare claims for Acthar received payment from Defendant, while only 35% of all specialists “receive payments from the pharmaceutical industry.” FAC ¶¶ 94, 104-06. In addition, eight of the nine doctors who prescribed the most Acthar to Plaintiff’s

members are rheumatologists or neurologists, and one specializes in sarcoidosis: all specialties that treat conditions for which Plaintiff has extensively alleged there are cheaper and more effective treatment options. See, e.g., id. ¶¶ 6, 13, 45-49, 84, 108.¹⁴ Taken together, these allegations plausibly suggest the payments to doctors were in exchange for prescribing Acthar, and not some other lawful purpose. See Eclectic Properties, 751 F.3d at 996 (quoting Starr, 652 F.3d at 1216) (“If there are two alternative explanations, one advanced by defendant and the other advanced by plaintiff, both of which are plausible, plaintiff’s complaint survives a motion to dismiss under Rule 12(b)(6). Plaintiff’s complaint may be dismissed only when defendant’s plausible alternative explanation is so convincing that plaintiff’s explanation is *implausible*.”).¹⁵

Although Plaintiff has not succeeded in each of its arguments, it has sufficiently alleged a pattern of racketeering activity.

3. Proximate Harm

Plaintiff alleges that the “effect of Mallinckrodt’s racketeering activity was to induce sales of Acthar that otherwise would not have been made in the absence of the illegal conduct and to maintain or raise the price of Acthar to a higher level than it would have commanded in the absence of the illegal conduct” and Plaintiff “suffered injuries when it reimbursed those prescriptions for Acthar that otherwise would not

¹⁴ Plaintiff cites a case noting that “compensation that exceeds fair market value is smoke . . . that makes fire plausible.” Opp’n at 19 (alterations omitted) (internal quotation marks omitted). However, Plaintiff does not allege the doctors were paid above fair market value.

¹⁵ Defendant moves to strike paragraph 109 of the FAC, which refers to a settlement between Defendant and the Department of Justice regarding illegal kickbacks. Mot. at 3, 10, 18. Defendant correctly notes that “the settlement is not proof that the underlying allegations were true,” Mot. at 3, but the allegation that Defendant reached a settlement is not “redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). The motion to strike is DENIED.

have been made and/or paid the higher prices that resulted from the illegal conduct.” FAC ¶¶ 154-55.

Defendant argues that this is insufficient because Plaintiff “does not contend that the alleged misconduct resulted in any Acthar prescriptions that were inappropriate given the patient’s particular condition” nor any Acthar prescriptions that were “harmful or ineffective.” Mot. at 23. As a factual matter, this is simply not correct. See, e.g., FAC ¶¶ 6 (“But other than [infantile spasms] and a handful of similarly rare conditions, Acthar is . . . either a drug of last resort or not known to be clinically effective”), 13 (Without the bribery scheme, “doctors would not otherwise be inclined to prescribe what for most purposes is an antiquated and expensive drug that requires refrigeration and injection when cheaper, more effective pills and remedies were available”), 46 (“there remains a lack of evidence to support the use of Acthar for most indications”), 49 (“it was expensive to produce, difficult to apply, and (except for certain indications such as infantile spasms) not known to be more effective than simpler, cheaper, and more widely available drugs”), 108 (Defendant “knew that in order to increase the prescription rates of Acthar, the Prescribing Doctors would need to prescribe Acthar in situations in which it was not called for and in lieu of considerably more cost-effective medications”), 128 (“[B]ut for Mallinckrodt’s kickback scheme and illegal co-pay assistance through CDF, prescription rates for Acthar would have been lower, and Humana members would have received different care from their physicians that was more effective, less harmful, or more cost effective than doses of Acthar”).

And as a legal matter, Defendant has not shown why this is relevant. Plaintiff’s “damages do not depend on the effectiveness of the” Acthar that Plaintiff paid for, but rather on “the inflationary effect that [Defendant’s] allegedly fraudulent behavior had on the price of [Acthar].” In re Avandia Mktg., Sales Practices & Prod. Liab. Litig.,

804 F.3d 633, 640 (3d Cir. 2015).¹⁶ Defendant's reliance on Ironworkers Local Union 68 v. AstraZeneca Pharm., LP, 634 F.3d 1352 (11th Cir. 2011) is misplaced. In Ironworkers, the alleged false representation was "concerning the drug's safety and efficacy in that use." Id. at 1363. The Eleventh Circuit held that a plaintiff must allege that the misrepresentation about the drug's safety and efficacy affected the doctor's prescription decision. Without any direct evidence, the court posited that "a plaintiff must allege that she not only paid for the drug, but also that its prescription was medically unnecessary or inappropriate." Id. Here, Plaintiff explicitly alleges that the doctors, who were themselves allegedly making false representations, would not have prescribed Acthar absent the allegedly illegal conduct. Therefore, allegations of indirect evidence are unnecessary.¹⁷

Defendant cites Holmes v. Sec. Inv'r Prot. Corp., 503 U.S. 258 (1992), which opines that "the less direct an injury is, the more difficult it becomes to ascertain the amount of a plaintiff's damages attributable to the violation, as distinct from other, independent, factors." Id. at 269. But Holmes does not stand for the proposition that proximate harm cannot be established any time it is difficult to ascertain damages. Rather, as the Ninth Circuit recently noted, this is one of the "three practical factors" that describe the "direct relation" requirement for proximate cause. Painters, 943 F.3d at 1249. Under this first

¹⁶ The Ninth Circuit cited Avandia with approval in Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd., 943 F.3d 1243, 1257 (9th Cir. 2019).

¹⁷ To the extent Ironworkers can be interpreted to eliminate insurance companies' ability to bring lawsuits against drug manufacturers for fraud, see 634 F.3d at 1360, 1364, this Court, along with the Third Circuit and other courts in this district, see Opp'n at 21 (citing Avandia, 804 F.3d at 641 n.45 and In re Lidoderm Antitrust Litig., 2017 WL 679367, at *22 n.32 (N.D. Cal. Feb. 21, 2017)), respectfully disagrees. Further, unlike in Ironworkers where the plaintiff potentially could have uncovered the alleged fraud through preauthorization, Plaintiff here already required preauthorization but alleges the doctors made false representations as part of that process.

factor, courts are to determine “whether it would be *too difficult* to ascertain what damages are attributable to Defendants’ alleged RICO violation, as opposed to factors other than, and independent of, Defendants’ alleged misrepresentations.” *Id.* (emphasis added). Further, Defendant has not explained how damages would be too difficult to ascertain merely because some prescriptions may have been medically necessary. To the contrary, Defendant implies it would be quite easy to “review the propriety of each Acthar prescription that [Plaintiff] covered” and determine “its medical necessity.” *See* Mot. at 23.¹⁸

Defendant also cites United Food & Commercial Workers Cent. Pennsylvania & Reg’l Health & Welfare Fund v. Amgen, Inc., 400 F. App’x 255 (9th Cir. 2010), which held that the plaintiff had “failed to plead a cognizable theory of proximate causation that links [defendant’s] alleged misconduct to [plaintiff’s] alleged injury.” *Id.* at 257. In Amgen, the plaintiff alleged that defendant drug manufacturer had “concealed adverse test results while promoting [its drugs] for various off-label uses.” *Id.* The Ninth Circuit held that there was an “attenuated causal chain” involving 1) an industry reference guide’s inclusion of the drug as treatment for anemia of cancer, 2) Medicare’s and third-party payor’s decisions to cover the drug for anemia of cancer, and 3) the doctors’ decision to prescribe the drug for anemia of cancer. *Id.* None of those third parties were alleged to have participated in any wrongdoing. In contrast, here the doctors were allegedly bribed to prescribe Acthar and were participants in the RICO conspiracy. That causal link is far from attenuated.¹⁹ Where the doctors are alleged to

¹⁸ The other relevant Holmes factor, “whether there are more directly injured victims we can count on to hold Defendants liable” also weighs in favor of proximate causation. Painters, 943 F.3d at 1252. Because of the co-pay assistance, Plaintiff and other insurers are “the most direct victims of those who suffered economic injury.” *Id.*

¹⁹ The other cases cited by Defendant are similarly distinguishable in that the doctors were not alleged to be part of the criminal activity. *See* UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 134 (2d Cir. 2010) (“the conduct

be a part of the scheme, and to have made false statements themselves, the doctors' prescription decisions do not break the causal chain. Moreover, the Ninth Circuit has now held that even unknowing doctors do not constitute an intervening cause. Painters, 943 F.3d at 1257-58 (to hold "that prescribing physicians' and pharmacy benefit managers' decisions constitute an intervening cause to sever the chain of proximate cause" would insulate drug manufacturers "from liability for their fraudulent marketing schemes, as they could continuously hide behind prescribing physicians and pharmacy benefit managers," which is "not the purpose the requirement of proximate cause is intended to serve").

Similarly, Health Care Serv. Corp. v. Olivares, No. 2:10-CV-221-TJW-CE, 2011 WL 4591913 (E.D. Tex. Sept. 2, 2011), report and recommendation adopted, No. 2:10-CV-221-DF-CE, 2011 WL 4591915 (E.D. Tex. Sept. 30, 2011) is distinguishable because the alleged fraudulent conduct was the marketing of defendant's drugs for off-label use. Id. at *1. The plaintiff failed to allege "that any doctors or other health care professional relied on any . . . misrepresentation promoting an off-label use" or that any misrepresentations "were made directly to it." Id. at *7. The complaint failed even to allege when plaintiff added defendant's drug to its approved list or the "circumstances [under which] those drugs were added." Id. Here, Plaintiff has alleged that the doctors prescribed Acthar because of the bribes and the availability of the co-pay assistance funds, and the false certifications from

directly causing the harm was distinct from the conduct giving rise to the fraud" where doctors prescribed defendant's drug because of misinformation about the drug, not bribes, and plaintiff's harm was not based on over-prescription of drugs, but plaintiff's reliance on third parties to place the drug on their list of approved drugs and subsequent failure to negotiate the price of the drug at a lower level); Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., 873 F.3d 574, 577 (7th Cir. 2017) ("The absence of data leaves a serious problem in showing plausible causation" where the alleged fraud "may not have changed their prescribing practices at all"). Moreover, as Defendant concedes, Reply at 11, their "persuasiveness" has been "call[ed] into question" by Painters.

Defendant and the doctors directly caused Plaintiff to pay for Acthar in an amount and for a price higher than it otherwise would have absent the alleged illegal conduct. Like in Painters, Plaintiff here is the direct recipient of the false statement. 943 F.3d at 1251 (“Plaintiffs’ alleged injury is that they purchased . . . prescriptions for which they would not have paid ***had they been warned*** about [the drug’s] risk of bladder cancer.” (emphasis added)).

Plaintiff has sufficiently alleged the Acthar Enterprise’s conduct proximately caused its injury.

Defendant’s motion to dismiss Counts Four and Five is DENIED.

C. State Law Claims (Counts Six through Ten)

Defendant contends that because Plaintiff’s unfair competition, consumer fraud and deceptive trade practices, insurance fraud, and unjust enrichment claims “rest on the same factual allegations or legal theories” as the antitrust and RICO claims, they should be dismissed for the same reasons as those claims. Mot. at 25. Even if this were so, because the Court denies Defendant’s motion to dismiss the RICO claims, the state law claims survive as well. Defendant’s motion to dismiss counts six through eight and ten is DENIED.

As to the tortious interference claim, which alleges that Defendant interfered with Plaintiff’s contracts with its members by providing co-pay assistance, FAC ¶ 191, Defendant notes that accepting co-pay assistance is not a breach of the insurance agreement that requires members to pay their share of costs for prescription drugs, Mot. at 25. As noted above, the OIG guidance states that co-pay assistance, even if from an illegal fund, “will count toward a beneficiary’s [true out-of-pocket] expenditures.” RJN, Ex. A at 9. Therefore, Plaintiff has not alleged that its members breached their contract.²⁰ Count Ten is DISMISSED with leave to amend.

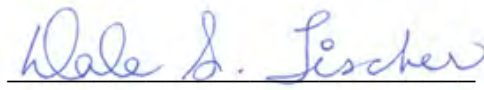
²⁰ The additional provision identified in Plaintiff’s opposition is more convincing. Opp’n at 24 (contract provision that “specifies that Humana ‘will not pay for any share of . . . drug costs’ for drugs obtained through a

IV. CONCLUSION

Counts One through Three and Ten are DISMISSED with leave to amend.²¹ An amended complaint may be filed and served no later than April 10, 2020. Failure to file by that date will waive the right to do so. The Court does not grant leave to add new defendants or new claims. Leave to add new defendants or new claims must be sought by a separate, properly noticed motion.

IT IS SO ORDERED.

Date: March 9, 2020



Dale S. Fischer
United States District Judge

manufacturer's 'patient assistance program.'"). However, because this was not included in the FAC, the Court does not consider it at this time.

²¹ Although the Court does not dismiss the RICO-based counts, Plaintiff is free to amend those claims consistent with the deficiencies identified in this order.

EXHIBIT K

Table of Out of State Authorities I

Count VII
Relevant Insurance Fraud Statutes & Lack of Independent, Private
Enforcement Mechanisms (or Legal Defenses in Lieu)

State Act	Permitted Enforcement Mechanism
Alaska Stat. §§ 21.36.360, et seq.	Civil penalties only for government enforcer, Alaska Stat. §§ 21.36.910; <i>O.K. Lumber Co., Inc. v. Providence Washington Ins. Co.</i> 759 P.2d 523, 526 (Alaska 1988) (holding that no private right of action is implied)
Ariz. Rev. Stat. §§ 20-463, et seq.	Civil penalties only for government enforcer, Ariz. Rev. Stat. § 20-466.02
Ark. Code §§ 23-66-501, et seq.	Civil penalties only for government enforcer, Ark. Code § 23-66-512(1)(B)
Cal. Ins. Code §§ 1871, et seq.	Private enforcement only after conviction, <i>Farmers Ins. Grp. Of Companies v. Workers' Comp. Appeals Bd.</i> , 128 Cal. Rptr. 2d 353, 355 (Cal. Dist. Ct. App. 2002), <i>review denied</i> (holding that insurance company could pursue civil proceedings to enforce criminal restitution order)
Conn. Gen. Stat. §§ 53a-215, et seq.	Criminal penalties only, Conn. Gen. Stat. § 53a-215(d)
Colo. Rev. Stat. § 10-1-128, et seq.	Civil penalties only for government enforcer, Colo. Rev. Stat. § 10-1-128(e)
Fla. Stat. §§ 817.234, et seq.	Private enforcement only after conviction, Fla. Stat. § 817.234(5)
Ga. Code Ann. §§ 33-1-9, et seq.	Criminal penalties only, Ga. Code § 33-1-9(d), (e)
Iowa Code Ann. §§ 505.1, et seq.	Civil penalties only for government enforcer, Iowa Code Ann. § 505.7A

State Act	Permitted Enforcement Mechanism
740 Ill. Comp. Stat. 92/1, et seq.; (ii) 720 Ill. Comp. Stat. 5/17-10.5	<p>(i) Qui tam action in the name of the State only, 740 Ill. Comp. Stat. 92/15; <i>Advanced Physicians, S.C. v. Provena Glenwood Med. Imaging</i>, 127 N.E.3d 546, 552 (Ill. App. Ct. 2018) (noting that the Act is a whistleblower law under which “interested” persons may proceed only with the Attorney General’s consent because the state is the real party in interest)</p> <p>(ii) Open civil penalties, 720 Ill. Comp. Stat. 5/17-10.5(e)</p> <p>In lieu of lack of private enforcement defense:</p> <p>(1) Claim under Act must be dismissed on the ground that pleadings for claims sounding in fraud require specificity, <i>see Abazari v. Rosalind Franklin Univ. of Med. & Sci.</i>, 40 N.E.3d 264, 270 (Ill. App. Ct. 2015); <i>Mitchell v. Norman James Constr. Co.</i>, 684 N.E. 2d 872, 938 (Ill. App. Ct. 1997), and allegations in Complaint fail to meet this requirement.</p> <p>(2) HCSC fails to allege actual injury from the alleged violation. <i>See Greer v. Illinois Hous. Dev. Auth.</i>, 524 N.E.2d 561, 572 (Ill. 1988) (requiring plaintiff to demonstrate the alleged conduct caused it to suffer injury in fact).</p> <p>(3) Claim to recover damages for an injury done to property barred by five year statute of limitations. 735 Ill. Comp. Stat. 5/13-205.</p>
Ind. Code §§ 35-43-5-4.5, et seq.	Criminal penalties only, Ind. Code §§ 35-43-5-4.5
Kan. Stat. Ann. §§ 40-2,118, et seq.	Criminal penalties only, Kan. Stat. Ann. § 40-2,118(e), (f)
Ky. Rev. Stat. §§ 304.47-011, et seq.	Private enforcement only after conviction, Ky. Rev. Stat. § 304.47-020(6), <i>Readnour v. Gibson</i> , 452 S.W.3d 617, 621 (Ky. Ct. App. 2014) (holding that “KRS 304.47-020 provides for a private right of action—but only where there has been a ‘criminal adjudication of guilt’”)
La. Stat. Ann. §§ 22:1924, et seq.	Criminal penalties only, La. Stat. Ann. § 22:1924A(1)
Me. Rev. Stat. Ann. tit. 24-A, § 2186	Civil penalties only for government enforcer, Me. Rev. Stat. Ann. tit. 24-A, § 2186(6)
Mass. Ann. Laws ch. 266, § 111A et seq.	Criminal penalties only, Mass. Ann. Laws ch. 266, § 111A

State Act	Permitted Enforcement Mechanism
Md. Code Ins. §§ 27-401, et seq.	Civil penalties only for government enforcer, Md. Code Ins. § 27-408(c)(1), (3)
Mich. Stat. §§ 500.4511, et seq.	Criminal penalties only, Mich. Stat. § 500.4511
Minn. Stat. §§ 609.611, et seq.	Criminal penalties only, Minn. Stat. § 609.611, Subd. 3
Miss. Code Ann. §§ 71-3-69, et seq.	Criminal penalties only, Miss. Code Ann. § 71-3-69
Mo. Rev. Stat. §§ 375.99, et seq.	Civil penalties only for government enforcer, Mo. Rev. Stat. § 375.994(4), (5)
Mont. Code §§ 33-1-1202, et seq.	Civil penalties only for government enforcer, Mont. Code § 33-1-1211
Neb. Rev. Stat. §§ 44-6604, et seq.	Civil penalties only for government enforcer, Neb. Rev. Stat. § 44-6607(1)
Nev. Rev. Stat. §§ 686A.2815, et seq.	Criminal penalties only, Nev. Rev. Stat. §§ 686A.291, 686A.292
N.H. Rev. Stat. §§ 638:20, et seq.	Criminal penalties only, N.H. Rev. Stat. § 638:20.IV(a)

State Act	Permitted Enforcement Mechanism
N.J. Stat. §§ 17:33A, et seq.	<p>Open civil penalties, N.J. Stat. § 17:33A-7</p> <p>In lieu of lack of private enforcement defense:</p> <p>(1) Claim under New Jersey Insurance Fraud Prevention Act must be dismissed on the ground that a claim of statutory insurance fraud must be pled with particularity, <i>see Aetna Health, Inc. v. Carabasi</i>, 2006 WL 66460, at *2 (N.J. Super. Ct. App. Div. Jan. 13, 2006), and allegations in Complaint fail under that standard.</p> <p>(2) HCSC fails to allege actual injury from the alleged violation. N.J. Stat. § 17:33A-7(a) (“Any insurance company damaged as the result of a violation of any provision of this act may sue therefor.”); <i>accord Allstate New Jersey Ins. Co. v. Lajara</i>, 117 A.3d 1221, 1231 (N.J. 2015) (“The insurance company must also prove a fourth element—that it was ‘damaged as a result of a violation of [the IFPA].’”).</p> <p>(3) HCSC fails to allege that it complied with the procedures provided in the New Jersey Insurance Fraud Prevention Act. <i>See</i> § 17:33A-7(c) (“A claimant under this section shall mail a copy of the initial claim, amended claim, counterclaims, briefs and legal memoranda to the [Attorney General] at the time of filing of such documents with the court wherein the matter is pending.”).</p>
N.M. Stat. §§ 59A-16C-1, et seq.	Civil penalties only for government enforcer, N.M. Stat. §§ 59A-16C-4(E), 59A-16C-10(E)
N.Y. Penal Law §§ 176.00, et seq.	Criminal penalties only, N.Y. Penal Law §§ 176.10, 176.15, 176.20, 176.25, 176.30, 176.35
N.C. Gen. Stat. §§ 58-2-160, et seq.	Private enforcement only after conviction, N.C. Gen. Stat. § 58-2-161; <i>see also Harleysville Mut. Ins. Co. v. Gray</i> , No. 1:11CV234, 2012 WL 2568147, at *6 (W.D.N.C. July 2, 2012) (holding that the statute only permits a plaintiff to bring a civil cause of action for insurance fraud after the defendant has been convicted)
N.D. Cent. Code §§ 26.1-01, et seq.	Civil penalties only for government enforcer, N.D. Cent. Code § 26.1-01-03.1
Ohio Rev. Code §§ 2913.47, et seq.	Criminal penalties only, Ohio Rev. Code § 2913.47(C)
Okla. Stat. tit. 36, §§ 101, et seq.	Civil penalties only for government enforcer, Okla. Stat. tit. 36, §§ 1207, 1211

State Act	Permitted Enforcement Mechanism
Or. Rev. Stat. §§ 165.692, et seq.	Criminal penalties only, Or. Rev. Stat. §§ 165.692, 165.696, 165.990
18 Pa. Stat. and Cons. Stat. Ann. §§ 4117	<p>Open civil penalties, 18 Pa. Stat. § 4117(g)</p> <p>In lieu of lack of private enforcement defense:</p> <p>(1) Claim under Act must be dismissed on the ground that averments of fraud must be pled with particularity, Pa. R. Civ. P. 1019(b), and allegations in Complaint fail under that standard.</p> <p>(2) HCSC fails to allege actual injury from the alleged violation. <i>See</i> 18 Pa. Stat. § 4117(g) (“An insurer damaged as a result of a violation of this section may sue therefore.”).</p> <p>(3) Claim under Act founded on fraud barred by two year statute of limitations. 42 Pa. Stat. § 5524.</p>
S.C. Code §§ 38-55-570, et seq.	Civil penalties only for government enforcer, S.C. Code § 38-55-550
Tenn. Code Ann. §§ 56-53-101, et seq.	<p>Open civil penalties, Tenn. Code Ann. § 56-53-107</p> <p>In lieu of lack of private enforcement defense:</p> <p>(1) Claim under Tennessee Insurance Fraud Act must be dismissed on the ground that claims sounding in fraud must be “stated with particularity.” Tenn. R. Civ. P. 9.02.</p> <p>(2) HCSC fails to allege actual injury from the alleged violation. <i>See</i> Tenn. Code Ann. § 56-53-107(a)(1) (“Any person injured in the person’s business or property by reason of a violation of § 56-53-103 may recover for the injury from the person or persons violating § 56-53-103.”).</p> <p>(3) Claim for treble damages under Tennessee Insurance Fraud Act barred by three year statute of limitations. § 56-53-107(2)(c); <i>see also</i> § 56-53-107(e) (five year statute of limitations applies for actions not seeking treble damages).</p>
Tex. Penal Code Ann. §§ 35.01, et seq.	Criminal penalties only, Texas Penal Code § 35.02

State Act	Permitted Enforcement Mechanism
Utah Code §§ 31A-31-103, et seq.	Civil penalties only for government enforcer, Utah Code § 31A-31-109; <i>Machan v. UNUM Life Ins. Co. of Am.</i> , 116 P.3d 342, 347-49 (Utah 2005) (holding that another provision of Utah’s insurance code, Section 31A-26-301, did not create a private right of action for an insured against an insurer using the U.S. Supreme Court’s four-factor test from <i>Cort v. Ash</i> , 422 U.S. 66, 78 (1975) as guidance)); <i>Buckner v. Kennard</i> , 99 P.3d 842, 853 (Utah 2004) (“Utah courts have rarely, if ever, found a Utah statute to grant an implied private right of action.”); <i>Miller v. Weaver</i> , 66 P.3d 593, 598 (Utah 2003) (“In the absence of language expressly granting a private right of action in the statute itself, the courts of this state are reluctant to imply a private right of action based on state law.”)
Wis. Stat. §§ 943.395, et seq.	Criminal penalties only, Wis. Stat. § 943.395(2)
Wyo. Stat. §§ 26-1-101, et seq.	Civil penalties only for government enforcer, Wyo. Stat. § 26-1-107; <i>see also Nat’l Surety Corp. v. CJM Hospitality, LLC</i> , Nos. 12-CV-03-F, 12-CV-101-F, 2013 WL 12161452, at *4–5 (D. Wyo. Nov. 18, 2013) (citing <i>Sorenson v. State Farm Auto. Ins. Co.</i> , 234 P.3d 1233, 1243 (Wyo. 2010); <i>Herrig v. Herrig</i> , 844 P.2d 487, 494 (Wyo. 1992)) (holding that the civil penalties in Wyo. Stat. Ann. § 26-1-107 do not create a private right of action given the absence of an express provision establishing one and the inclusion of other means of enforcement in the statute)

EXHIBIT L

Table of Out of State Authorities II

Counts III, IV & V

Relevant States' Authorities Adopting

Rule of Reason for Nonprice Vertical Restraints

State	Authorities
Arizona	<i>Wedgewood Inv. Corp. v. International Harvester Co.</i> , 613 P.2d 620, 624–25 (Ariz. Ct. App. 1979) (expressly adopting <i>GTE Sylvania</i>).
Arkansas	<i>Edgar Lumber Co. v. Cornie Stave Co.</i> , 130 S.W. 452, 454–55 (Ark. 1910) (upholding a railroad owner's right to contract to haul timber exclusively for one person, firm, or operation and citing to a Virginia state case finding a similar contract to be a reasonable restraint of trade); <i>see also Vincent v. Indep. Gin Corp.</i> , 237 S.W.2d 486, 487–88 (Ark. 1951) (finding that a contract wherein a cotton planter who sold his gin agreed that for five years he would use that gin to process all the cotton he grew was not an invalid restraint of trade).
California	<i>Bert G. Gianelli Distributing Co. v. Beck & Co.</i> , 172 Cal. App. 3d 1020, 1045, 1047–48 (1985) (expressly adopting <i>GTE Sylvania</i>).
Colorado	<i>Hutton v. Memorial Hospital</i> , 824 P.2d 61, 63 (Colo. App. 1991) (adopting rule of reason).
Connecticut	<i>Hydro Air of Conn. v. Versa Techs.</i> , 599 F. Supp. 1119, 1122–23 (D. Conn. 1984) (applying rule of reason to federal and state antitrust law claims challenging exclusive distributorship); <i>Elida, Inc. v. Harmor Realty Corp.</i> , 413 A.2d 1226, 1230–31 (Conn. 1979) (noting that Connecticut antitrust statute incorporates federal antitrust law and the rule of reason has been applied to nonprice vertical restraints under federal law).
D.C.	D.C. Code § 28-4515 (providing that interpretations of federal law are a guide).
Florida	<i>Parts Depot Co. v. Fla. Auto Supply</i> , 669 So. 2d 321, 326 (Fla. Dist. Ct. App. 1996) (expressly adopting <i>GTE Sylvania</i>).
Hawaii	Haw. Rev. Stat. § 480-3 (construed in accordance with federal law); <i>Courbat v. Dahana Ranch, Inc.</i> , 141 P.3d 427, 435 n.6 (Haw. 2006) (same “in light of conditions in Hawaii”).
Idaho	Idaho Code § 48-102(3) (construed in accordance with federal law).

State	Authorities
Illinois	<i>International Parts v. Caterpillar, Inc.</i> , 631 N.E.2d 1258, 1264 (Ill. App. Ct. 1994) (holding that a vertical nonprice restraint was to be reviewed under the rule of reason).
Indiana	<i>Miller Brewing Co. v. Bartholemew County Beverage Co.</i> , 674 N.E.2d 193, 204–05 (Ind. Ct. App. 1996) (indicating in <i>dictum</i> that the court would apply rule of reason to a nonprice vertical restraint challenged under state antitrust law).
Iowa	Iowa Code § 553.2 (construed in accordance with federal law); <i>State v. Cedar Rapids Bd. of Realtors</i> , 300 N.W.2d 127, 128 (Iowa 1981) (holding that the rule of reason will generally apply to alleged restraints of trade challenged under state antitrust law claims).
Kansas	Kan. Stat. Ann. § 50-163(b) (construed in accordance with federal law); Kan. Stat. Ann. § 50-163(c) (exempting from state antitrust law any “reasonable restraint of trade or commerce” defined as a restraint that is “reasonable in view of all of the facts and circumstances of the particular case and does not contravene public welfare”).
Louisiana	<i>Plaquemine Marine v. Mercury Marine</i> , 859 So. 2d 110, 118 (La. Ct. App. 2003) (expressly adopting <i>GTE Sylvania</i>).
Maine	<i>McKinnon v. Honeywell Intern., Inc.</i> , 977 A.2d 420, 426 (Me. 2009) (holding that Maine antitrust statute is construed in accordance with federal law); <i>State v. MaineHealth</i> , No. CIV.A.CV-00-548, 2001 WL 1711006, at *2 (Me. Super. Ct. July 26, 2001) (holding that courts ordinarily apply the rule of reason to determine whether practice is prohibited by state antitrust law).
Maryland	<i>Nat. Design, Inc. v. Rouse Co.</i> , 485 A.2d 663, 666–68 (Md. 1984) (holding that federal antitrust precedent is a guide and indicating in <i>dictum</i> that the court would adopt <i>GTE Sylvania</i> to assess whether a nonprice vertical restriction constitutes an unreasonable restraint of trade under state antitrust law); <i>Eastside Vend Distribs., Inc. v. Coca-Cola Enters., Inc.</i> , No. 24-C-04-003998, 2006 WL 1516012, at *17 (Md. Cir. Ct. May 8, 2006) (holding that <i>GTE Sylvania</i> applies to nonprice vertical restraints).
Massachusetts	<i>Parikh v. Franklin Med. Ctr.</i> , 940 F. Supp. 395, 401 (D. Mass. 1996) (applying <i>GTE Sylvania</i> to federal and Massachusetts law claims challenging exclusive dealing arrangement).

State	Authorities
Michigan	<i>McDill v. McDonald Coop. Dairy Co.</i> , 283 N.W.2d 819, 823 (Mich. Ct. App. 1979) (expressly adopting <i>GTE Sylvania</i> in case brought under previous state antitrust statute); <i>see also</i> Mich. Comp. Laws § 445.784(2) (providing that “courts shall give due deference” to federal precedent, “including, without limitation, the doctrine of . . . the rule of reason”).
Minnesota	<i>State by Humphrey v. Road Constructors, Inc.</i> , 474 N.W.2d 224, 225 (Minn. Ct. App. 1991) (adopting <i>GTE Sylvania</i> in an antitrust action brought by the state); <i>Hough Transit, Ltd. v. Nat’l Farmers Org.</i> , 472 N.W.2d 358, 360–61 (Minn. Ct. App. 1991) (holding that the Section 325D.51 of the Minnesota Antitrust Law codifies the “rule of reason” and that an exclusive arrangement between a milk co-op and delivery driver was not a per se illegal refusal to deal under Section 325D.53, subd. 1(3)); <i>see also State by Humphrey v. Alpine Air Prods.</i> , 490 N.W.2d 888, 894 (Minn. Ct. App. 1992) (holding that Minnesota antitrust law should be construed in accordance with federal law).
Mississippi	<i>Walker v. U-Haul Co.</i> , 734 F.2d 1068, 1071 (5th Cir. 1984) (upholding district court’s application of <i>GTE Sylvania</i> to federal and Mississippi state antitrust claims challenging an alleged vertical restraint of trade).
Missouri	Mo. Rev. Stat. § 416.141 (construed in accordance with federal law); <i>Marc’s Restaurant, Inc. v. CBS, Inc.</i> , 730 S.W.2d 582, 586 (Mo. Ct. App. 1987) (same); <i>see also Mo. Portland Cement Co. v. Denny Concrete Co.</i> , 499 S.W.2d 432, 435–37 (Mo. 1973) (applying an analysis consistent with the rule of reason to evaluate the validity of an exclusive requirements contract under a prior state antitrust statute).
Montana	<i>Smith v. Video Lottery Consultants, Inc.</i> , 858 P.2d 11 (Mont. 1993) (noting that § 30-14-205 is modeled after § 1 of the Sherman Act and that where “the statutes are similar, we will give due weight to the federal courts’ interpretation of this type of alleged antitrust violation”).
Nebraska	Neb. Rev. Stat. § 59-829 (construed in accordance with federal law when same or similar language to federal antitrust law); <i>Arthur v. Microsoft Corp.</i> , 676 N.W.2d 29, 35, 38 (Neb. 2004) (interpreting Neb. Rev. Stat. § 59-829 as aiming for “uniform application” of state and federal antitrust laws to the extent its consistent with the state antitrust statute’s purpose).

State	Authorities
Nevada	Nev. Rev. Stat. § 598A.050 (construed in accordance with federal law); <i>Boulware v. Nev. Dep't of Human Res.</i> , 960 F.2d 793, 800–01 (9th Cir. 1992) (same).
New Hampshire	N.H. Rev. Stat. § 356:14 (providing that interpretations of federal law are a guide); <i>Minuteman, LLC v. Microsoft Corp.</i> , 795 A.2d 833, 836 (N.H. 2002) (finding that the legislature “expressly encouraged” and it has “long been the practice” for courts to apply federal case law to interpret state antitrust law).
New Mexico	N.M. Stat. § 57-1-15 (construed in accordance with federal law); <i>Smith Mach. Corp. v. Hesston, Inc.</i> , 694 P.2d 501, 505 (N.M. 1985) (holding that New Mexico courts should apply federal antitrust case law when no state cases are directly on point).
New York	<i>Anheuser-Busch, Inc. v. Abrams</i> , 520 N.E.2d 535, 538–39 (N.Y. 1988), <i>rev'g</i> 512 N.Y.S.2d 802 (N.Y. App. Div. 1987) (holding that the Donnelly Act should generally be construed in accordance with federal law and that although vertical territorial restraints are not per se legal, the Act only prohibits “unreasonable” restraints of trade).
North Carolina	<i>Stearns v. GenRad, Inc.</i> , 564 F. Supp. 1309, 1315–16, 1318 (M.D.N.C. 1983), <i>aff'd</i> , 752 F.2d 942 (4th Cir. 1984) (applying the rule of reason to state and federal antitrust claims challenging alleged vertical restraints).
North Dakota	<i>Ag Acceptance Corp. v. Glinz</i> , 684 N.W.2d 632 (N.D. 2004) (applying federal antitrust case law to determine whether tying arrangement violated N.D. Cent. Code §§ 51-08.1-01, et seq).
Oregon	Or. Rev. Stat. § 646.715(2) (providing that interpretations of federal law are persuasive authority); <i>Willamette Dental Group, P.C. v. Oregon Dental Services Corp.</i> , 882 P.2d 637, 640–41 (Or. Ct. App. 1994) (interpreting state antitrust law based on federal case law in the absence of Oregon state court decisions).
Pennsylvania	<i>Maxwell v. Schaefer</i> , 112 A.2d 69, 71–72 (holding that defendant in contract dispute failed to show how exclusive distribution agreement was an unreasonable restraint of trade); <i>see also Collins v. Main Line Bd. of Realtors</i> , 304 A.2d 493, 496 (Pa. 1973) (applying federal precedent to determine whether an agreement unreasonably restrained trade).
Puerto Rico	<i>Gen. Gases & Supplies Corp. v. Shoring & Forming Sys., Inc.</i> , 2001 P.R. Offic. Trans. 54 (P.R. 2001) (holding that interpretations

State	Authorities
	of federal law are a guide but Puerto Rico's "particular economic reality" requires courts to be even more flexible and to generally apply the rule of reason to local antitrust claims).
Rhode Island	<i>Auburn News Co. v. Providence Journal Co.</i> , 504 F. Supp. 292, 300, 304 (D.R.I. 1980), <i>rev'd on other grounds</i> , 659 F.2d 273 (1st Cir. 1981) (applying rule of reason to state and federal antitrust claims challenging an exclusive dealership); <i>see also ERI Max Entm't, Inc. v. Streisand</i> , 690 A.2d 1351, 1353, n.1 (R.I. 1997) (holding that the state antitrust statute is construed in accordance with federal law).
South Carolina	<i>Blanton Enters. v. Burger King Corp.</i> , 680 F. Supp. 753, 765–68 (D.S.C. 1988) (applying <i>GTE Sylvania</i> to state and federal antitrust claims challenging an alleged nonprice vertical restraint); <i>Walter A. Wood Mowing & Reaping Co. v. Greenwood Hardware Co.</i> , 55 S.E. 973, 974–76 (S.C. 1906) (applying an analysis consistent with the rule of reason to evaluate the legality of a territorial restraint under a prior state antitrust statute).
South Dakota	<i>Assam Drug Co. v. Miller Brewing Co.</i> , 798 F.2d 311, 313–15 (8th Cir. 1986) (applying <i>GTE Sylvania</i> to state antitrust claim challenging a vertical nonprice restraint).
Tennessee	<i>State ex rel. Att'y Gen. v. Burley Tobacco Growers, Co-operative Ass'n</i> , 2 Tenn. App. 674, 681 (1926) (holding that the rule of reason applies to Tennessee antitrust law).
Utah	Utah Code § 76-10-3118 (providing that interpretations of federal law are a guide); <i>Evans v. State</i> , 963 P.2d 177, 181 (Utah 1998) (looking to federal and other state courts for guidance to interpret Utah antitrust statute).
Vermont	Vt. Stat. Ann. tit. 9, § 2453(b) (providing that interpretations of federal law are a guide).
Virginia	<i>Thompson-Everett, Inc. v. National Cable Advertising</i> , 850 F. Supp. 470, 480–82 (E.D. Va. 1994), <i>aff'd</i> , 57 F.3d 1317 (4th Cir. 1995) (applying <i>GTE Sylvania</i> to state and federal antitrust claims challenging vertical exclusive distributorships).
West Virginia	W. Va. Code § 47-18-16 (construed in accordance with federal law).
Wisconsin	<i>Grams v. Boss</i> , 294 N.W.2d 473, 480 (Wis. 1980), <i>overruled on other grounds by Beidel v. Sideline Software Inc.</i> , 842 N.W.2d 240 (Wis. 2013) (holding that federal case law controls interpretation of

State	Authorities
	Wisconsin antitrust statute); <i>Ford Motor Co. v. Lyons</i> , 405 N.W.2d 354, 367 (Wis. Ct. App. 1987) (same).
Wyoming	<i>State v. Langley</i> , 84 P.2d 767, 772–74 (Wyo. 1938) (recognizing the common law principles relating to unreasonable restraints of trade and looking to federal and other state court decisions when assessing constitutionality of state competition statute).

EXHIBIT M

Table of Out of State Authorities III

Count V
Relevant State Unfair and Deceptive Trade Practices Acts &
Limitations Periods (or Legal Defenses in Lieu)

State Act	Limitation Period (Other Legal Defenses Where > 5 Years)
Ark. Code Ann. §§ 4-88-101, et seq.	5 years from occurrence of violation, Ark. Code Ann. § 4-88-115
Ariz. Rev. Stat. §§ 44-1522, et seq.	1 year after the cause of action accrues, Ariz. Rev. Stat. § 12-541(5)
Cal. Bus. & Prof. Code §§ 17200, et seq.	4 years after the cause of action accrues, Cal. Bus. & Prof. Code § 17208
Colo. Rev. Stat. § 6-1-105, et seq.	3 years from the unlawful act or after a person discovers or should have discovered it, which may be extended by 1 year if plaintiff proves defendant engaged in conduct to induce plaintiff not to commence suit, Colo. Rev. Stat. § 6-1-115
D.C. Code §§ 28-3901, et seq.	3 years from the time the right to maintain the action accrues, D.C. Code § 12-301(8)
Fla. Stat. §§ 501.201, et seq.	4 years from occurrence of actual damages, Fla. Stat. § 95.11(3)(f)
Idaho Code §§ 48-601, et seq.	2 years after the cause of action accrues, Idaho Code § 48-619
815 Ill. Comp. Stat. 505/1, et seq.	3 years after the cause of action accrues, 815 Ill. Comp. Stat. 505/10a(e)
Ind. Code §§ 24-5-0.5-1, et seq.	2 years after the occurrence of the deceptive act, Ind. Code § 24-5-0.5-5
Kan. Stat. Ann. §§ 50-623, et seq.	3 years from occurrence of violation for claims seeking actual damages and 1 year from occurrence of violation for claims seeking civil penalties, Kan. Stat. Ann. § 60-512
La. Stat. Ann. § 51:1401, et seq.	1 year from the unlawful act, La. Stat. Ann. § 51:1409

State Act	Limitation Period (Other Legal Defenses Where > 5 Years)
Me. Rev. Stat. Ann. tit. 5, §§ 207, et seq.	<p>6 years after the cause of action accrues, Me. Rev. Stat. Ann. tit. 14, § 752</p> <p>In lieu of statute of limitations defense: Claim under Act is barred on the ground that it permits only injunctive relief for private plaintiffs, Me. Rev. Stat. Ann. tit. 10, § 1213, and allegedly unlawful conduct discontinued over five years before HCSC filed its Complaint.</p>
Mass. Ann. Laws ch. 93A, et seq.	<p>4 years after the cause of action accrues, Mass. Gen. Laws Ann. ch. 260, § 5A</p>
Mich. Stat. §§ 445.901, et seq.	<p>6 years after the occurrence or 1 year after the last payment in a transaction involving the unlawful act, whichever comes later, Mich. Stat. § 445.911(7)</p> <p>In lieu of statute of limitations defense: Claim under Act is barred on the ground that Mich. Stat § 445.904(1)(a) exempts conduct that is part of a transaction already regulated by other federal or state laws and regulations. This exemption applies when the general transaction at issue, not the alleged misconduct, is specifically authorized under other laws administered by a regulatory board or officer acting under state or federal statutory authority, as is the case for the allegedly unlawful conduct in HCSC's Complaint. <i>See Liss v. Lewiston-Richards, Inc.</i>, 478 Mich. 203, 212-13 (Mich. 2007); <i>Smith v. Globe Life Ins. Co.</i>, 460 Mich. 446, 464-65 (Mich. 1999). The conduct at issue is part of a transaction for prescription drug coverage, which is regulated by federal statute and the Centers for Medicare & Medicaid Services.</p>
Minn. Stat. §§ 325D.43, et seq.	<p>6 years from the occurrence of the alleged statutory violation, Minn. Stat. § 541.05</p> <p>In lieu of statute of limitations: Claim under Act is barred on the ground it permits only injunctive relief and attorneys' fees for private plaintiffs, Minn. Stat. § 325D.45; <i>Superior Edge, Inc. v. Monsanto Co.</i>, 964 F. Supp. 2d 1017, 1041 (D. Minn. 2013) (citing <i>Dennis Simmons, D.D.S., P.A. v. Modern Aero, Inc.</i>, 603 N.W.2d 336, 339 (Minn. Ct. App. 1999)); <i>Damon v. Groteboer</i>, 937 F. Supp. 2d 1048, 1070 (D. Minn. 2013); <i>Alsides v. Brown Institute, Ltd.</i>, 592 N.W.2d 468, 476 (Minn. Ct. App. 1999), and allegedly unlawful conduct discontinued over five years before HCSC filed its Complaint.</p>
Miss. Code Ann. §§ 75-24-1, et seq.	<p>3 years after the cause of action accrues, Miss. Code Ann. § 15-1-49</p>

State Act	Limitation Period (Other Legal Defenses Where > 5 Years)
Mo. Rev. Stat. §§ 407.010, et seq.	5 years from the time the plaintiff has knowledge of the wrong and at least nominal damage or knowledge of something that puts plaintiff on notice to inquire further, Mo. Rev. Stat. § 516.120(2)
Neb. Rev. Stat. §§ 59-1601, et seq.	4 years after the cause of action accrues, Neb. Rev. Stat. § 59-1612
Nev. Rev. Stat. §§ 598.0903, et seq.	4 years after the cause of action accrues (which does not start until party discovers or should have discovered by due diligence the deceptive trade practice), Nev. Rev. Stat. Ann. § 11.190(d)
N.H. Rev. Stat. §§ 358-A:1, et seq.	3 years from the time the plaintiff knew, or reasonably should have known, of the unlawful conduct, N.H. Rev. Stat. § 358-A:3(IV-a)
N.M. Stat. Ann. §§ 57-12-1, et seq.	4 years from the time the plaintiff sustains actual injury and discovers, or should have discovered through reasonable diligence, the facts essential to the cause of action, N.M. Stat. Ann. § 37-1-4
N.Y. General Business Law §§ 349, et seq.	3 years from the time the plaintiff was injured, N.Y. C.P.L.R. 214(2)
N.C. Gen. Stat. §§ 75-1.1, et seq.	4 years after the cause of action accrues, N.C. Gen. Stat. § 75-16.2
N.D. Cent. Code §§ 51-15-01, et seq.	<p>6 years after the cause of action accrues, N.D. Cent. Code, § 28-01-16</p> <p>In lieu of statute of limitations defense: Claim under Act is barred on the ground that N.D. Cent. Code §§ 51-15-01, <i>et seq.</i> only applies to statements made directly to the private party in connection with the sale or advertisement of merchandise. <i>Thimjon Farms P'ship v. First Int'l Bank & Trust</i>, 837 N.W.2d 327, 337–38 (N.D. 2013). In the Complaint, HCSC only alleges that certifications were made to HCSC and only in connection with a determination regarding prescription drug coverage.</p>
Or. Rev. Stat. §§ 646.605, et seq.	1 year from the discovery of the unlawful method, act or practice. Or. Rev. Stat. § 646.638
73 Pa. Stat. and Cons. Stat. Ann. §§ 201-1, et seq.	<p>6 years after the cause of action accrues, 42 Pa. Stat. and Cons. Stat. Ann. § 5527(b)</p> <p>In lieu of statute of limitations defense: Claim under Act is barred on the ground that it requires the goods purchased to be for “personal, family, or household purposes,” 73 Pa. Stat. Ann. § 201-9.2, and the purchases made by HCSC alleged in the Complaint were not made for any of the enumerated purposes.</p>

State Act	Limitation Period (Other Legal Defenses Where > 5 Years)
S.C. Code Ann. §§ 39-5-10, et seq.	3 years after discovery of the unlawful conduct, S.C. Code Ann. § 39-5-150
S.D. Codified Laws §§ 37-24-1, et seq.	4 years after the occurrence or discovery of the conduct, S.D. Codified Laws § 37-24-33
Utah Code Ann. §§ 13-11-1, et seq.	3 years after the cause of action accrues, Utah Code Ann. § 78B-2-305
Vt. Stat. Ann. tit. 9, § 2451, et seq.	6 years after the cause of action accrues, Vt. Stat. Ann. tit. 12, § 511 In lieu of statute of limitations defense: Claim under Act is barred on the ground that a “consumer” who can sue for relief under the Act is defined as a “person who purchases . . . goods or services . . . for his or her use or benefit or the use or benefit of a member of his or her household, or in connection with the operation of his or her household,” Vt. Stat. Ann. tit. 9, § 2451a, and HCSC does not meet this definition, as its alleged purchases were not made for any of the enumerated purposes.
Va. Code Ann. §§ 59.1-196, et seq.	2 years after the cause of action accrues. Va. Code Ann. § 59.1-204.1
W. Va. Code §§ 46A-6-101, et seq.	1 year after the right to bring the action accrues, W. Va. Code § 55-2-12(c)
Wis. Stat. § 100.18, et seq.; Wis. Stat. § 100.20, et seq.	3 years after the occurrence of the unlawful act or practice, Wis. Stat. § 100.18
Wyo. Stat. Ann. § 40-12-101, et seq.	1 year after the required written notice is furnished to the alleged violator (which must be furnished either within 1 year after the unlawful deceptive trade practice or within 2 years following the consumer transaction, whichever occurs first), Wyo. Stat. Ann. § 40-12-109

EXHIBIT N

Table of Out of State Authority IV

Counts III & IV
Relevant State Antitrust Acts Injury Requirements

State Acts	Authorities
<p>Ariz. Rev. Stat. §§ 44-1403, et seq. (Count III)</p> <p>Ariz. Rev. Stat. §§ 44-1402, et seq. (Count IV)</p>	<p>Ariz. Rev. Stat. § 44-1408 (“A person threatened with injury or injured in his business or property by a violation of this article may bring an action for . . . damages sustained . . .”).</p>
<p>Cal. Bus. & Prof Code §§ 17200, et seq. (Count III)</p> <p>Cal. Bus. & Prof Code §§ 16700, et seq. (Count IV)</p>	<p>Cal. Bus. & Prof Code § 16750(a) (“Any person who is injured in his or her business or property by reason of anything forbidden or declared unlawful by this chapter, may sue therefor . . .”); <i>Chicago Title Ins. Co. v. Great Western Fin. Corp.</i>, 69 Cal.2d 305, 317–318 (Cal. 1968) (holding that plaintiff bringing a civil action for damages under California’s antitrust statute must “allege and prove that his business or property has been injured” from the reduction in competition).</p>
<p>Conn. Gen. Stat. Ann. § 35-24, et seq. (Counts III & IV)</p>	<p>Conn. Gen. Stat. Ann. § 35-35 (“[A]ny person, including, but not limited to, a consumer, injured in its business or property by any violation of the provisions of this chapter shall recover treble damages, together with a reasonable attorney's fee and costs.”); <i>Roncari Dev. Co. v. GMG Enters., Inc.</i>, 718 A.2d 1025, 1031 (Conn. Super. Ct. 1997) (holding that plaintiff must plead injury to its business or property as a result of the alleged violation to state a cause of action under Connecticut Antitrust Act).</p>
<p>D.C. Code §§ 28-4503, et seq. (Count III)</p> <p>D.C. Code §§ 28-4502, et seq. (Count IV)</p>	<p>D.C. Code § 28-4508(a) (“Any person who is injured in that person's business or property by reason of anything forbidden by this chapter may bring a civil action for damages . . .”).</p>

State Acts	Authorities
Fla. Stat. §§ 501.201, et seq. (Counts III & IV)	Fla. Stat. § 501.211(2) (“In any action brought by a person who has suffered a loss as a result of a violation of this part, such person may recover actual damages, plus attorney’s fees and court costs as provided in s. 501.2105.”); <i>Rollins, Inc. v. Butland</i> , 951 So.2d 860, 869 (Fla. Dist. Ct. App. 2006) (holding that claims for damages under Florida’s unfair competition statute require the plaintiff to show (1) a deceptive act or unfair practice; (2) causation; and (3) actual damages).
Haw. Rev. Stat. §§ 480, et seq. (Count III) Haw. Rev. Stat. §§ 480-1, et seq. (Count IV)	Haw. Rev. Stat. § 480-13(a)(1) (“[A]ny person who is injured in the person’s business or property by reason of anything forbidden or declared unlawful by this chapter may sue for damages sustained by the person.”).
740 Ill. Comp. Stat. 10/3, et seq. (Counts III & IV)	740 Ill. Comp. Stat. 10/7(2) (“Any person who has been injured in his business or property, or is threatened with such injury, by a violation of Section 3 of this Act may maintain an action in the Circuit Court for damages, or for an injunction, or both, against any person who has committed such violation.”); <i>Gilbert’s Ethan Allen Gallery v. Ethan Allen, Inc.</i> , 620 N.E.2d 1349, 1351–53 (Ill. App. Ct. 1993) (holding that federal precedent should be used in construing state antitrust law); <i>Collins v. Associated Pathologists, Ltd.</i> , 676 F. Supp. 1388, 1405–06 (C.D. Ill. 1987) (applying analysis under federal antitrust laws to state antitrust claims).
Iowa Code §§ 553.5, et seq. (Counts III & IV)	Iowa Code § 553.12 (“[A] person who is injured or threatened with injury by conduct prohibited under this chapter may bring suit to . . . [r]ecover actual damages resulting from conduct prohibited under this chapter [or] [r]ecover, at the court’s discretion, exemplary damages [if certain conditions are met].”); <i>Davies v. Genesis Med. Ctr.</i> , 994 F. Supp. 1078, 1103 (S.D. Iowa 1998) (dismissing state antitrust claim based on same reasoning for dismissing claim under Section 2 of the Sherman Act because Iowa courts “are required by section 553.2 to give considerable weight to federal cases construing similar section of the Sherman Act”) (citing <i>Neyens v. Roth</i> , 326 N.W.2d 294, 297–98 (Iowa 1932)).

State Acts	Authorities
Kansas Stat. Ann. §§ 50-101, et seq., §§ 50-158, et seq. (Count IV)	Kansas Stat. Ann. § 50-161(b) (“[A]ny person who may be damaged or injured by any agreement, monopoly, trust, conspiracy or combination which is declared unlawful by the Kansas restraint of trade act shall have a cause of action against any person causing such damage or injury. Such action may be brought by any person who is injured in such person's business or property by reason of anything forbidden or declared unlawful by the Kansas restraint of trade act . . .”); <i>O’Brien v. Leegin Creative Leather Prods., Inc.</i> , 277 P.3d 1062, 1076 (Kan. 2012) (holding that under Kansas antitrust statutes, “a plaintiff must show that the plaintiff was injured or damaged by the defendant’s forbidden behavior”).
Md. Code Ann., Com. Law § 11-201, et seq. (Counts III & IV)	Md. Code Ann., Com. Law § 11-209(b)(2)(i) (“A person whose business or property has been injured or threatened with injury by a violation of § 11-204 of this subtitle may maintain an action for damages or for an injunction or both against any person who has committed the violation . . .”).
Mass. Gen. L. Ch. 93A, et seq. (Count III)	Mass. Gen. L. ch. 93A, § 11) (“Any person who engages in the conduct of any trade or commerce and who suffers any loss of money or property, real or personal, as a result of the use or employment by another person who engages in any trade or commerce of an unfair method of competition or an unfair or deceptive act or practice declared unlawful by section two or by any rule or regulation issued under paragraph (c) of section two may, as hereinafter provided, bring an action in the superior court . . . for damages and such equitable relief, including an injunction, as the court deems to be necessary and proper.”).
Me. Rev. Stat. Ann. tit. 10, §§ 1102, et seq. (Count III) Me. Rev. Stat. Ann. tit. 10, §§ 1101, et seq. (Count IV)	Me. Rev. Stat. Ann. tit. 10, § 1104 (“Any person . . . injured directly or indirectly in its business or property by any other person or corporation by reason of anything forbidden or declared to be unlawful by section 1101, 1102 or 1102-A, may sue for the injury in a civil action.”); <i>McKinnon v. Honeywell Intern., Inc.</i> , 977 A.2d 420, 426 (holding that a plaintiff must prove injury or damage before plaintiff can recover under Maine’s antitrust statute).

State Acts	Authorities
<p>Mich. Comp. Laws Ann. §§ 445.773, et seq. (Count III)</p> <p>Mich. Comp. Laws Ann. §§ 445.771, et seq. (Count IV)</p>	<p>Mich. Comp. Laws Ann. § 445.778(2) (“Any other person threatened with injury or injured directly or indirectly in his or her business or property by a violation of this act may bring an action for . . . actual damages sustained by reason of a violation of this act, and, as determined by the court, interest on the damages from the date of the complaint, taxable costs, and reasonable attorney's fees.”).</p>
<p>Minn. Stat. §§ 325D.52, et seq.; Minn. Stat. § 8.31, et seq. (Count III)</p> <p>Minn. Stat. §§ 325D.49, et seq. (Count IV)</p>	<p>Minn. Stat. § 325D.57 (“Any person, any governmental body, or the state of Minnesota or any of its subdivisions or agencies, injured directly or indirectly by a violation of sections 325D.49 to 325D.66, shall recover three times the actual damages sustained, together with costs and disbursements, including reasonable attorneys' fees.”).</p>
<p>Miss. Code Ann. §§ 75-21-3, et seq. (Counts III & IV)</p>	<p>Miss. Code Ann. § 75-21-9 (“Any person, natural or artificial, injured or damaged by a trust and combine as herein defined, or by its effects direct or indirect, may recover all damages of every kind sustained by him or it and in addition a penalty of five hundred dollars (\$500.00), by suit in any court of competent jurisdiction.”).</p>
<p>Mont. Code Ann. § 30-14-205 (Count IV)</p>	<p>Mont. Code Ann. § 30-14-222(1) (“A person who is or will be injured . . . may bring an action to enjoin an act that is in violation of 30-14-205 through 30-14-214 or 30-14-216 through 30-14-218 and for the recovery of damages.”).</p>
<p>Neb. Code Ann. §§ 59-802, et seq. (Count III)</p> <p>Neb. Code Ann. §§ 59-801, et seq. (Count IV)</p>	<p>Neb. Code Ann. § 59-821 (“Any person who is injured in his or her business or property by any other person or persons by a violation of sections 59-801 to 59-831, whether such injured person dealt directly or indirectly with the defendant, may bring a civil action in the district court in the county in which the defendant or defendants reside or are found . . . and shall recover actual damages or liquidated damages . . .”).</p>
<p>Nev. Rev. Stat. Ann. §§ 598A.060, et seq. (Counts III & IV)</p>	<p>Nev. Rev. Stat. Ann. § 598A.210(2) (“Any person injured or damaged directly or indirectly in his or her business or property by reason of a violation of the provisions of this chapter may institute a civil action and shall recover treble damages, together with reasonable attorney fees and costs.”); <i>Nev. Recycling & Salvage, Ltd. V. Reno Disposal Co., Inc.</i>, 423 P.3d 605, 608 (Nev. 2018) (holding that plaintiffs lacked standing to bring state antitrust claims because they did not demonstrate any injuries to their business resulting from alleged violation).</p>

State Acts	Authorities
<p>N.H. Rev. Stat. Ann. §§ 356.1, et seq. (Count III)</p> <p>N.H. Rev. Stat. Ann. §§ 356.2, et seq. (Count IV)</p>	<p>N.H. Rev. Stat. Ann. § 356:11 (“Any person injured in his business or property by reason of a violation of this chapter may recover the actual damages sustained, and as determined by the court, the costs of the suit and reasonable attorney's fees regardless of whether that person dealt directly or indirectly with the defendant. If the trier of facts finds that the violation is willful or flagrant, they may increase damages to an amount not in excess of 3 times the actual damages sustained.”); <i>Donovan v. Digital Equip. Corp.</i>, 883 F. Supp. 775, 785, (D.N.H. 1994) (“[T]he court applies the federal antitrust standing requirements as this promotes the uniform construction of antitrust laws as contemplated.”) (granting summary judgment for lack of standing).</p>
<p>N.M. Stat. Ann. §§ 57-1-2, et seq. (Counts III & IV)</p>	<p>N.M. Stat. Ann. § 57-1-3 (“[A]ny person threatened with injury or injured in his business or property, directly or indirectly, by a violation . . . may bring an action . . .”)</p>
<p>N.Y. Gen. Bus. Law § 340, et seq. (Count IV)</p>	<p>N.Y. Gen. Bus. Law § 340(5) (“[A]ny person who shall sustain damages by reason of any violation of this section, shall recover three-fold the actual damages sustained thereby”); <i>Anheuser-Busch, Inc. v. Abrams</i>, 71 N.Y.2d 327, 335, 520 N.E.2d 535, 539 (1988) (“[T]he Donnelly Act—often called a “Little Sherman Act”—should generally be construed in light of Federal precedent and given a different interpretation only where State policy, differences in the statutory language or the legislative history justify such a result.”); <i>Stolow v. Greg Manning Auctions Inc.</i>, 258 F. Supp. 2d 236, 244 (S.D.N.Y.), <i>aff'd</i>, 80 F. App'x 722 (2d Cir. 2003) (“The Sherman Act and Donnelly Act claims are discussed as if one claim [including for injury purposes] because New York's antitrust law is modeled on the Sherman Act and should be construed in light of federal precedent.” (internal quotations omitted)).</p>
<p>N.C. Gen. Stat. §§ 75-2.1, et seq. (Count III)</p> <p>N.C. Gen. Stat. §§ 75-1, et seq. (Count IV)</p>	<p>N.C. Gen. Stat. § 75-16 (“If any person shall be injured or the business of any person, firm or corporation shall be broken up, destroyed or injured by reason of any act or thing done by any other person, firm or corporation in violation of the provisions of this Chapter, such person, firm or corporation so injured shall have a right of action on account of such injury done, and if damages are assessed in such case judgment shall be rendered in favor of the plaintiff and against the defendant for treble the amount fixed by the verdict.”).</p>

State Acts	Authorities
N.D. Cent. Code §§ 51-08.1-03, et seq. (Count III)	N.D. Cent. Code § 51-08.1-08(2) (“A person threatened with injury or injured in that person's business or property by a violation of [the Act] may bring an action for appropriate injunctive or other equitable relief, damages sustained and, as determined by the court, taxable costs and reasonable attorney’s fees.”).
N.D. Cent. Code §§ 51-08.1-02, et seq. (Count IV)	
Or. Rev. Stat. §§ 646.705, et seq. (Counts III & IV)	Or. Rev. Stat. § 646.780(1)(a) (“A person . . . injured in its business or property . . . may sue therefor and shall recover threefold the damages sustained.”).
10 L.P.R.A. §§ 257, et seq. (Count III)	10 L.P.R.A. § 269a (“Every person shall have the right to institute proceedings for injunctions before the Court of First Instance to prevent losses or damages to his business or property by any other person, by reason of acts or intended acts, forbidden or declared to be unlawful by this chapter.”).
10 L.P.R.A. §§ 260, et seq. (Count IV)	
R.I. Gen. Laws §§ 6-36-1, et seq. (Counts III & IV)	§ 6-36-11 (“Any person . . . injured in his or her business or property by reason of a violation of the [antitrust statute] may sue in superior court.”); § 6-36-2(b) (“This chapter shall be construed in harmony with judicial interpretations of comparable federal antitrust statutes insofar as practicable.”); <i>accord Siena v. Microsoft Corp.</i> , 796 A.2d 461 (R.I. 2002).
S.D. Codified Laws §§ 37-1-3.2, et seq. (Count III)	§ 37-1-14.3 (“A person injured in his business or property by a violation of this chapter may bring an action.”); <i>Byre v. City of Chamberlain</i> , 362 N.W.2d 69, 74 (S.D. 1985) (instructing that “great weight should be given to the federal cases interpreting the federal [antitrust] statute”).
S.D. Codified Laws §§ 37-1-3.1, et seq. (Count IV)	
Tenn. Code Ann. §§ 47-25-101, et seq. (Count IV)	§ 47-25-106 (“Any person who is injured or damaged by any such arrangement, contract, agreement, trust, or combination described in this part may sue.”); <i>Sherwood v. Microsoft Corp.</i> , 2003 WL 21780975 (Tenn. Ct. App. July 31, 2003) (noting “that the purposes of the TTPA are furthered by granting a private remedy to any person <i>injured by anticompetitive</i> conduct”).
Utah Code Ann. §§ 76-10-911, et seq. (Count III)	§ 76-10-3109(1)(a) (“A person who is a citizen of this state or a resident of this state and who is injured or is threatened with injury in his business or property by a violation of the Utah Antitrust Act may bring an action for injunctive relief and damages.”).
Utah Code Ann. §§ 76-10-3101, et seq. (Count IV)	
Vt. Stat. Ann. 9, §§ 2453, et seq. (Count III & IV)	§ 2465(a) (“Any person who sustains damages or injury as a result of any violation of State antitrust laws . . . may sue and recover from the violator.”).

State Acts	Authorities
W.Va. Code §§ 47-18-4, et seq. (Count III) W. Va. Code §§ 47-18-1, et seq. (Count IV)	§ 47-18-9 (“Any person who shall be injured in his business or property by reason of a violation of the provisions of this article may bring an action therefor.”).
Wis. Stat. §§ 133.03, et seq. (Count III) Wis. Stat. §§ 133.01, et seq. (Count IV)	§ 133.18(1)(a) (“[A]ny person injured, directly or indirectly, by reason of anything prohibited by this chapter may sue therefor.”).

EXHIBIT O

Table of Out of State Authorities V

Counts III & IV
Relevant State Antitrust Acts & Limitations Periods

State Act	Limitation Period
Ariz. Rev. Stat. §§ 44-1403, et seq. (Count III)	“An action . . . to recover damages is barred if it is not commenced within four years after the cause of action accrues.” Ariz. Rev. Stat. § 44-1410.
Ariz. Rev. Stat. §§ 44-1402, et seq. (Count IV)	
Cal. Bus. & Prof Code §§ 17200, et seq. (Count III)	“Any action to enforce [the Unfair Competition Law] shall be commenced within four years after the cause of action accrued.” Cal. Bus. & Prof. Code § 17208.
Cal. Bus. & Prof Code §§ 16700, et seq. (Count IV)	“Any civil action to enforce any cause of action for a violation of [the Cartwright Act] shall be commenced within four years after the cause of action accrued.” Cal. Bus. & Prof. Code § 16750(a).
Conn. Gen. Stat. Ann. § 35-24, et seq. (Count III & IV)	“Any action . . . shall be forever barred unless commenced within four years after the cause of action shall have accrued.” Conn. Gen. Stat. Ann. § 35-40.
D.C. Code §§ 28-4503, et seq. (Count III)	“An action . . . to recover damages is barred if the action is not commenced within four (4) years after the cause of action accrues . . .” D.C. Code Ann. § 28-4511(b).
D.C. Code §§ 28-4502, et seq. (Count IV)	
	<p>For the cited provisions, Florida’s unfair and deceptive trade practices statute: “Actions other than for recovery of real property shall be commenced . . . within four years” for “[a]n action founded on a statutory liability.” <i>See S. Motor Co. of Dade Cty. v. Doktorczyk</i>, 957 So. 2d 1215, 1216–17 (Fla. Dist. Ct. App. 2007) (“Section 95.11(3)(f), Florida Statutes (1996), covers ‘[a]n action founded on a statutory liability,’ which would apply to [a] FDUTPA claim.”).</p> <p>*See also the Florida antitrust statute (Fla. Stat. §§ 542.15 et seq.): “Any action . . . must be commenced within 4 years after the cause of action accrues.” Fla. Stat. § 542.26.</p>

State Act	Limitation Period
<p>Haw Code §§ 480, et seq. (Count III)</p> <p>Haw. Code §§ 480-1, et seq. (Count IV)</p>	<p>“Any action to enforce a cause of action arising under this chapter shall be barred unless commenced within four years after the cause of action accrues.” Haw. Code § 480-24.</p>
<p>740 Ill. Comp. Stat. 10/3, et seq. (Count III & IV)</p>	<p>“Any action for damages under this subsection is forever barred unless commenced within 4 years after the cause of action accrued.” 740 Ill. Comp. Stat. 10/7.</p>
<p>Iowa Code §§ 553.5, et seq. (Count III & IV)</p>	<p>“Suit . . . must be commenced within four years after the cause of action accrues.” Iowa Code § 553.16(2).</p>
<p>Kansas Stat. Ann. §§ 50-101, et seq., §§ 50-158, et seq. (Count IV)</p>	<p>“The following actions shall be brought within three (3) years: . . . [a]n action upon a liability created by a statute other than a penalty or forfeiture.” Kan. Stat. Ann. § 60-512(2).</p> <p><i>See</i> Kan. Stat. Ann. § 50-139 (“All actions brought to enforce this act shall be brought pursuant to chapter 60 of the Kansas Statutes Annotated, and amendments thereto.”); <i>O'Brien v. Leegin Creative Leather Prod., Inc.</i>, 294 Kan. 318, 351-55 (2012) (holding that the Kansas Restraint of Trade Act is governed by the three-year statute of limitations).</p>
<p>Md. Code Ann., Com. Law § 11-201, et seq. (Count III & IV)</p>	<p>“An action brought to enforce this subtitle shall be commenced within 4 years after the cause of action accrues.” Md. Code Ann., Com. Law § 11-209(d)(1).</p>
<p>Mass. Gen. L. Ch. 93A, et seq. (Count III)</p>	<p>“An action brought to enforce the provisions of this Act shall be barred unless commenced within four years after the cause of action accrued.” Mass. Gen. Laws Ch. 93, § 13.</p>
<p>Me. Rev. Stat. Ann. 10, §§ 1102, et seq. (Count III)</p> <p>Me. Rev. Stat. Ann. 10, §§ 1101, et seq. (Count IV)</p>	<p>“All civil actions shall be commenced within 6 years after the cause of action accrues and not afterwards.” Me. Rev. Stat. Ann. 14, § 752; <i>see McKinnon v. Honeywell Int'l, Inc.</i>, 977 A.2d 420, 424 (Me. 2009).</p>
<p>Mich. Comp. Laws Ann. §§ 445.773, et seq. (Count III)</p> <p>Mich. Comp. Laws Ann. §§ 445.771, et seq. (Count IV)</p>	<p>“An action . . . is barred if not commenced within 4 years after the claim of relief or cause of action accrues.” Mich. Comp. Laws Ann. § 445.781.</p>

State Act	Limitation Period
Minn. Stat. §§ 325D.52, et seq.; Minn. Stat. § 8.31, et seq. (Count III)	“An action . . . shall be forever barred unless commenced within four years of the date upon which the cause of action arose.” Minn. Stat. § 325D.64.
Minn. Stat. §§ 325D.49, et seq. (Count IV)	
Miss. Code Ann. §§ 75-21-3, et seq. (Count III & IV)	“All actions for which no other period of limitation is prescribed shall be commenced within three (3) years next after the cause of such action accrued, and not after.” Miss. Code. Ann. § 15-1-49(1).
Mont. Code Ann. 30-14-205 (Count IV)	“An action for relief not otherwise provided for must be commenced within 5 years after the cause of action accrues.” Mont. Code. Ann. § 27-2-231.
Neb. Code Ann. §§ 59-802, et seq. (Count III)	“Any action to enforce a claim for damages . . . shall be forever barred unless commenced within four years after the cause of action accrues.” Neb. Rev. Stat. Ann. § 59-1612.
Neb. Code Ann. §§ 59-801, et seq. (Count IV)	
Nev. Rev. Stat. Ann. §§ 598A.060, et seq. (Count III & IV)	“An action . . . is barred if it is not commenced . . . [w]ithin 4 years after the cause of action accrues, or if the cause of action is based upon a conspiracy in violation of this chapter, within 4 years after the plaintiff discovered, or by the exercise of reasonable diligence, should have discovered the facts relied upon for proof of the conspiracy.” Nev. Rev. Stat. Ann. § 598A.220(2)(a).
N.H. Rev. Stat. Ann. §§ 356.1, et seq. (Count III)	“An action . . . to recover damages is barred if it is not commenced within 4 years after the cause of action accrues.” N.H. Rev. Stat. Ann. § 356:12(II).
N.H. Rev. Stat. Ann. §§ 356.2, et seq. (Count IV)	
N.M. Stat. Ann. §§ 57-1-2, et seq. (Count III & IV)	“An action . . . is barred if it is not commenced within four years after the cause of action accrues or within four years after the plaintiff discovered, or by the exercise of reasonable diligence should have discovered, the facts relied upon for proof of the cause of action, whichever is later.” N.M. Stat. Ann. § 57-1-12.
N. Y. General Business Law § 340, et seq. (Count IV)	“An action to recover damages caused by a violation of this section must be commenced within four years after the cause of action has accrued.” N.Y. Gen. Bus. Law § 340(5).

State Act	Limitation Period
<p>N.C. Gen. Stat. §§ 75-2.1, et seq. (Count III)</p> <p>N.C. Gen. Stat. §§ 75-1, et seq. (Count IV)</p>	<p>“Any civil action brought under this Chapter to enforce the provisions thereof shall be barred unless commenced within four years after the cause of action accrues.” N.C. Gen. Stat. § 75-16.2.</p>
<p>N.D. Cent. Code §§ 51-08.1-03, et seq. (Count III)</p> <p>N.D. Cent. Code §§ 51-08.1-02, et seq. (Count IV)</p>	<p>“An action . . . to recover damages is barred if it is not commenced within four years after the claim for relief accrues.” N.D. Cent. Code § 51-08.1-10(2).</p>
<p>Or. Rev. Stat. §§ 646.705, et seq. (Count III & IV)</p>	<p>“An action . . . recover damages shall be commenced within four years after the cause of action accrued.’ Or. Rev. Stat. § 646.800(2).</p>
<p>10 L.P.R.A. §§ 257, et seq. (Count III)</p> <p>10 L.P.R.A. §§ 260, et seq. (Count IV)</p>	<p>“The judicial action to recover damages . . . shall be commenced within four (4) years after the cause of action accrued.” 10 L.P.R.A. § 268(c).</p>
<p>R.I. Gen. Laws §§ 6-36-1, et seq. (Count III & IV)</p>	<p>“Any action brought to enforce the provisions of this chapter shall be barred unless commenced within four (4) years after the cause of action arose, or if the cause of action is based upon a conspiracy in violation of this chapter, within four (4) years after the plaintiff discovered, or by the exercise of reasonable diligence should have discovered, the facts relied upon for proof of the conspiracy.” 6 R.I. Gen. Laws § 6-36-23.</p>
<p>S.D. Codified Laws §§ 37-1-3.2, et seq. (Count III)</p> <p>S.D. Codified Laws §§ 37-1-3.1, et seq. (Count IV)</p>	<p>“An action . . . to recover damages is barred if it is not commenced within four years after the claim for relief accrues.” S.D. Codified Laws § 37-1-14.4.</p>
<p>Tenn. Code Ann. §§ 47-25-101, et seq. (Count IV)</p>	<p>“The following actions shall be commenced within three (3) years from the accruing of the cause of action . . . [a]ctions for injuries to personal or real property.” Tenn. Code Ann. § 28-3-105(1); <i>See State ex rel. Leech v. Levi Strauss & Co.</i>, No. 79-722-III, 1980 WL 4696, at *1 (Tenn. Ch. Sept. 25, 1980) (applying the three-year statute of limitations for property torts, then listed at T.C.A. § 28-305, in a case where the state of Tennessee sued in its capacity as a purchaser of the defendants’ products).</p>

State Act	Limitation Period
Utah Code Ann. §§ 76-10-911, et seq. (Count III) Utah Code Ann. §§ 76-10-3101, et seq. (Count IV)	“Any other action pursuant to this act is barred if it is not commenced within four years after the cause of action accrues.” Utah Code Ann. § 76-10-3117(2).
Vt. Stat. Ann. 9, §§ 2453, et seq. (Count III & IV)	“A civil action . . . shall be commenced within six years after the cause of action accrues and not thereafter.” Vt. Stat. Ann. 12, § 511.
W.Va. Code §§ 47-18-4, et seq. (Count III) W. Va. Code §§ 47-18-1, et seq. (Count IV)	“Any action brought to enforce the provisions of this article shall be barred unless commenced within four years after the cause of action arose, or if the cause of action is based upon a conspiracy in violation of this article, within four years after the plaintiff discovered, or by the exercise of reasonable diligence should have discovered the facts relied upon for proof of the conspiracy.” W. Va. Code Ann. § 47-18-11.
Wis. Stat. §§ 133.03, et seq. (Count III) Wis. Stat. §§ 133.01, et seq. (Count IV)	“A civil action for damages or recovery of payments under this chapter is barred unless commenced within 6 years after the cause of action accrued.” Wis. Stat. § 133.18(2).

EXHIBIT 34



Superior Court of California, County of Alameda
 Rene C. Davidson Alameda County Courthouse
 1225 Fallon Street
 Oakland, CA 94612

Receipt Nbr: 922289
 Clerk: jmoyer
 Date: 06/02/2020

Type	Case Number	Description	Amount
Filing	RG20056354	Other Ex Parte	\$20.00

Total Amount Due: \$20.00
 Prior Payment:
 Current Payment: \$20.00
 Balance Due: \$.00
 Overage:
 Excess Fee:
 Change:

Payment Method:
 Cash:
 Check: \$20.00

ENDORSED
FILED
ALAMEDA COUNTY

MAY 29 2020

CLERK OF THE SUPERIOR COURT
By JERRIE MOYER
Deputy

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Attorneys for Plaintiff
Health Care Service Corporation
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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a Mallinckrodt
ARD Inc., f/k/a Questcor Pharmaceuticals, Inc.), and
MALLINCKRODT plc,

Defendants.

Case No. RG20056354

**STIPULATION TO AMEND
BRIEFING SCHEDULE AND
[PROPOSED] ORDER**

Dept: 19
Judge: Hon. Stephen Kaus

Action Filed: February 27, 2020

STIPULATION AND [PROPOSED] ORDER RE BRIEFING SCHEDULE

1 **WHEREAS**, Plaintiff Health Care Service Corp. (“HCSC”) filed its Complaint in this
2 action on February 27, 2020 and personally served the Summons and Complaint on Defendants
3 Mallinckrodt ARD, LLC and Mallinckrodt plc (collectively “Mallinckrodt”) on March 5, 2020.

4 **WHEREAS**, prior to the assignment of this case to Department 19 and while the Court
5 was closed to filings of civil pleadings motions to help prevent the spread of the coronavirus,
6 HCSC and Mallinckrodt submitted to the Court a stipulated order in which they agreed to a
7 briefing schedule on Mallinckrodt’s pleadings motions under which Mallinckrodt would “serve
8 and (if the Court is accepting such filings) file a demurrer or answer to the Complaint ... [on] May
9 20, 2020,” HCSC would “file any brief in opposition to a demurrer [on] June 5, 2020,” and
10 Mallinckrodt would “file a reply in support of a demurrer [on] June 19, 2020.”

11 **WHEREAS**, in their stipulation, the parties also requested an extension of the page limits
12 to allow 25 pages for the opening memorandum, 25 pages for the opposition, and 12 pages for the
13 reply, given that the claims in the Complaint cover five different categories of conduct and arise
14 under more than 30 states’ laws.

15 **WHEREAS**, on May 12, 2020 the Court entered an order approving HCSC and
16 Mallinckrodt’s stipulation on a briefing schedule and page-limit extensions.

17 **WHEREAS**, on May 19, 2020, the Court entered an order setting the hearing on
18 Mallinckrodt’s coming pleading motions for June 26, 2020, and Mallinckrodt requested a hearing
19 reservation for that date but did not receive a response.

20 **WHEREAS**, on May 20, 2020 Mallinckrodt placed in the Court’s filing drop box and
21 served a Notice of Demurrer and Demurrer to HCSC’s Complaint, a Notice of Motion and Motion
22 to Strike Allegations from Plaintiff HCSC’s Complaint, and a Request for Judicial Notice in
23 Support of the Defendant Mallinckrodt Entities’ Demurrer and Motion to Strike.

24 **WHEREAS**, on May 22, 2020, this case was reassigned to Department 19 and all
25 previously scheduled hearings were vacated.

26 **WHEREAS**, on May 27, 2020, the Court’s clerk returned Mallinckrodt’s May 20 filing
27 for the lack of a hearing reservation number from Department 19.
28

1 **WHEREAS**, on May 28, 2020 Mallinckrodt reserved a hearing date in Department 19 for
 2 its demurrer and motion to strike of August 5, 2020, reservation #(s) R-2179414 -Demurrer & R-
 3 2179416 -Motion To Strike, filed its papers with the new reservation numbers, department
 4 assignment, and hearing date, and it re-served its papers with the updated hearing information.

5 **NOW THEREFORE**, pursuant to Cal. R. Court, Rules 3.501(17) and 3.503, the parties
 6 submit this Stipulation and [Proposed] Order and request the Court's confirmation of the Court's
 7 May 12 Order approving the page-limit extensions for briefing on Mallinckrodt's pleading
 8 motions and the Court's consent to the revised briefing scheduled proposed herein. HCSC and
 9 Mallinckrodt agree that (1) HCSC should have up until June 23, 2020 to file responses to
 10 Mallinckrodt's demurrer, motion to strike, and request for judicial notice, and (2) Mallinckrodt
 11 should have until July 21, 2020 to file reply briefs.

12 **IT IS SO STIPULATED.**

14 Dated: May 29, 2020

By: Matthew Weiler (with consent)
 Todd M. Schneider (SBN 158253) by DES

Jason H. Kim (SBN 220279)
 Matthew S. Weiler (SBN 236052)
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*Counsel for Plaintiff Health Care Service
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Dated: May 29, 2020

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*Attorneys for Defendants Mallinckrodt ARD
LLC and Mallinckrodt plc*

IT IS SO ORDERED:

Dated: _____

By: _____
HON. JUDGE STEPHEN KAUS
OF THE SUPERIOR COURT
FOR THE COUNTY OF ALAMEDA

COURTESY COPY
 ENDORSED
 FILED
 ALAMEDA COUNTY
 MAY 29 2020
 CLERK OF THE SUPERIOR COURT
 JERRIE MOYER Deputy

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Attorneys for Plaintiff

Health Care Service Corporation

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 11 should have until July 21, 2020 to file reply briefs.

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14 Dated: May 29, 2020

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*Counsel for Plaintiff Health Care Service
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Dated: May 29, 2020

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LLC and Mallinckrodt plc*

IT IS SO ORDERED:

Dated: _____

By: _____
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OF THE SUPERIOR COURT
FOR THE COUNTY OF ALAMEDA

ARNOLD & PORTER KAYE SCHOLER LLP

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Attorneys for Plaintiff
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HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

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1 **WHEREAS**, Plaintiff Health Care Service Corp. (“HCSC”) filed its Complaint in this
2 action on February 27, 2020 and personally served the Summons and Complaint on Defendants
3 Mallinckrodt ARD, LLC and Mallinckrodt plc (collectively “Mallinckrodt”) on March 5, 2020.

4 **WHEREAS**, prior to the assignment of this case to Department 19 and while the Court
5 was closed to filings of civil pleadings motions to help prevent the spread of the coronavirus,
6 HCSC and Mallinckrodt submitted to the Court a stipulated order in which they agreed to a
7 briefing schedule on Mallinckrodt’s pleadings motions under which Mallinckrodt would “serve
8 and (if the Court is accepting such filings) file a demurrer or answer to the Complaint ... [on] May
9 20, 2020,” HCSC would “file any brief in opposition to a demurrer [on] June 5, 2020,” and
10 Mallinckrodt would “file a reply in support of a demurrer [on] June 19, 2020.”

11 **WHEREAS**, in their stipulation, the parties also requested an extension of the page limits
12 to allow 25 pages for the opening memorandum, 25 pages for the opposition, and 12 pages for the
13 reply, given that the claims in the Complaint cover five different categories of conduct and arise
14 under more than 30 states’ laws.

15 **WHEREAS**, on May 12, 2020 the Court entered an order approving HCSC and
16 Mallinckrodt’s stipulation on a briefing schedule and page-limit extensions.

17 **WHEREAS**, on May 19, 2020, the Court entered an order setting the hearing on
18 Mallinckrodt’s coming pleading motions for June 26, 2020, and Mallinckrodt requested a hearing
19 reservation for that date but did not receive a response.

20 **WHEREAS**, on May 20, 2020 Mallinckrodt placed in the Court’s filing drop box and
21 served a Notice of Demurrer and Demurrer to HCSC’s Complaint, a Notice of Motion and Motion
22 to Strike Allegations from Plaintiff HCSC’s Complaint, and a Request for Judicial Notice in
23 Support of the Defendant Mallinckrodt Entities’ Demurrer and Motion to Strike.

24 **WHEREAS**, on May 22, 2020, this case was reassigned to Department 19 and all
25 previously scheduled hearings were vacated.

26 **WHEREAS**, on May 27, 2020, the Court’s clerk returned Mallinckrodt’s May 20 filing
27 for the lack of a hearing reservation number from Department 19.
28

1 **WHEREAS**, on May 28, 2020 Mallinckrodt reserved a hearing date in Department 19 for
 2 its demurrer and motion to strike of August 5, 2020, reservation #(s) R-2179414 -Demurrer & R-
 3 2179416 -Motion To Strike, filed its papers with the new reservation numbers, department
 4 assignment, and hearing date, and it re-served its papers with the updated hearing information.

5 **NOW THEREFORE**, pursuant to Cal. R. Court, Rules 3.501(17) and 3.503, the parties
 6 submit this Stipulation and [Proposed] Order and request the Court's confirmation of the Court's
 7 May 12 Order approving the page-limit extensions for briefing on Mallinckrodt's pleading
 8 motions and the Court's consent to the revised briefing scheduled proposed herein. HCSC and
 9 Mallinckrodt agree that (1) HCSC should have up until June 23, 2020 to file responses to
 10 Mallinckrodt's demurrer, motion to strike, and request for judicial notice, and (2) Mallinckrodt
 11 should have until July 21, 2020 to file reply briefs.

12 **IT IS SO STIPULATED.**

14 Dated: May 29, 2020

By: Matthew Weiler (with consent)
 Todd M. Schneider (SBN 158253) by DES

Jason H. Kim (SBN 220279)
 Matthew S. Weiler (SBN 236052)
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IT IS SO ORDERED:

Dated: _____

By: _____
HON. JUDGE STEPHEN KAUS
OF THE SUPERIOR COURT
FOR THE COUNTY OF ALAMEDA

EXHIBIT 35

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Mallinckrodt ARD LLC

Superior Court of California, County of Alameda
Rene C. Davidson Alameda County Courthouse

Health Care Service Corp

Plaintiff/Petitioner(s)

VS.

Mallinckrodt ARD LLC

Defendant/Respondent(s)

(Abbreviated Title)

No. RG20056354

Stipulation and Order Re: Other Ex
Parte Granted

IT IS ORDERED that the Defendant's Stipulation and Order Re: Other Ex Parte is granted and the terms are approved.

Dated: 06/02/2020



Judge Stephen Kaus

EXHIBIT 36

FILED BY FAX
ALAMEDA COUNTY

June 19, 2020

CLERK OF
THE SUPERIOR COURT
By Keisha Ghee, Deputy

CASE NUMBER:
RG20056354

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendants

Case No.: RG20056354

Hon. Stephen Kaus

**CASE MANAGEMENT CONFERENCE
STATEMENT FOR JUNE 23, 2020 CASE
MANGEMENT CONFERENCE**

1 **I. INTRODUCTION**

2 Plaintiff Health Care Service Corporation and Defendants Mallinckrodt ARD LLC
3 (“Mallinckrodt”) and Mallinckrodt plc have met and conferred in advance of the Case Management
4 Conference scheduled for June 23, 2020.

5 **II. PLAINTIFF’S STATEMENT OF DISPUTED FACTUAL AND LEGAL ISSUES**

6 Health Care Service Corp. (“HCSC”), a Blue Cross licensee that provides health care
7 services and purchases pharmaceutical products for thousands of patients, brings claims against
8 Mallinckrodt relating to anticompetitive conduct and fraudulent sales and marketing practices for
9 H.P.Acthar® Gel (“Acthar”). Acthar is an adrenocorticotrophic hormone (“ACTH”) treatment with
10 humble beginnings. Developed in 1952, it is derived from the pituitary glands slaughtered pigs, and
11 is a critical treatment used to control infantile seizures, a rare disease with around 1,200 cases per
12 year. After Mallinckrodt’s predecessor Questcor Pharmaceuticals, Inc. (“Questcor”) acquired the
13 drug in 2001, the price leapt 97,500% from \$40 per vial in 2001 to over \$39,000 in 2018 for that
14 same vial.

15 HCSC alleges this price increase is the result of a complex, multipart scheme involving a
16 monopoly, the abuse of exclusive distribution agreements, bribery, racketeering, fraud, and other
17 deceptive and unfair practices that have imposed exorbitant costs on those financially responsible for
18 the costs of the drug, including third-party payors (“TPPs”) like HCSC here. No other explanation
19 exists for these unconscionable price increases, which by far outstrip the prices of any inputs, such as
20 pigs.

21 Mallinckrodt manufactures Acthar and orchestrated a monopoly in the market for ACTH
22 drugs, through its control of pricing and distribution of Acthar. Questcor initiated a series of
23 escalating price increases, while at the same time taking measures to ensure that competing ACTH
24 products and channels of distribution were eliminated.

25 Starting in 2007, CuraScript SD became the exclusive distributor of Acthar.
26 Questcor/Mallinckrodt consolidated this control by operating Express Scripts in a vertically
27 integrated operation. This dynamic allowed Questcor/Mallinckrodt to control prices of Acthar. In
28 2013, Questcor acquired the rights to develop a synthetic ACTH drug called Synacthen Depot

1 (“Synacthen”). Through Questcor, Mallinckrodt kept Synacthen off the market by out-bidding
2 potential buyers at the last minute and has ‘mothballed’ Synacthen after acquiring it.

3 Mallinckrodt’s multi-faceted campaign of fraudulent sales and marketing tactics further
4 inflated prices. Mallinckrodt used a charitable foundation, the Chronic Disease Fund (“CDF”), for
5 the illegal purpose of paying patient co-pays for Acthar prescriptions only, instead of any medically
6 appropriate therapy. Mallinckrodt created, controlled, and financed multiple CDF co-pay funds for
7 patients prescribed Acthar, and only Acthar, under the guise of creating disease-specific funds such
8 as the “MS Exacerbation Fund.” The co-pay funds expanded the prescription base of Acthar beyond
9 infant spasms to other diseases, while helping to overcome any patient or doctor resistance to
10 prescribing Acthar due to the high cost.

11 To encourage wider prescription, Mallinckrodt developed and promoted an “off label” dosing
12 regimen that only required patients to use Acthar for five days, even though the typical regimen is
13 several vials over two to three weeks. Although highly lucrative for Mallinckrodt, this dosing
14 regimen was not FDA approved, not indicated on the Acthar label, and not supported by clinical
15 evidence of its efficacy. However, this shorter dosing protocol lent credibility to Mallinckrodt’s
16 unsupported claim of superior tolerability for Acthar because patients reported fewer side effects and
17 made the price seem affordable when compared with the cost of administering the drug according to
18 the label’s instructions.

19 Finally, Mallinckrodt funneled millions of dollars to doctors through the facade of speaking
20 engagements and sham clinical research studies to promote the foregoing and reward high
21 prescribers of the drug. These payments were necessary because in addition to Acthar’s expense, its
22 mechanism of action requires refrigeration and injection into the body, making it more difficult for
23 patients to use and doctors less inclined to prescribe it. HCSC contends that under the circumstances
24 these payments for sham speaking engagements and studies are ‘bribes’ and not legitimate education
25 or marketing programs.

26 The foregoing facts give rise to the following legal issues:

27 1. Whether Defendant fraudulently concealed any of the foregoing facts.
28

2. Whether Defendant violated New Jersey's Racketeer Influenced and Corrupt Organizations Act ("NJ RICO"), N.J.S.A. §§ 2C:41-1(b), 2C:41-2(c), et al.
3. Whether Defendant violated Section 2C:41-2(d) of NJ RICO by conspiring to engage in the foregoing acts.
4. Whether Defendant violated state antitrust laws by monopolizing the market for ACTH.
5. Whether Defendant violated state antitrust law by entering into agreements in restraint of trade relating to Acthar.
6. Whether Defendant engaged in unfair competition or unfair, unconscionable, deceptive or fraudulent acts or practices in violation of state consumer protection statutes.
7. Whether Defendant's conduct constitutes fraud under state laws.
8. Whether Defendant violated state insurance fraud laws.
9. Whether Defendant profited and benefited unjustly from the foregoing facts.

III. DEFENDANTS' STATEMENT OF DISPUTED FACTUAL AND LEGAL ISSUES

HCSC is one of the nation's largest healthcare insurers. It claims that for eight years it paid too much for too many prescriptions for Acthar, despite having contemporaneously reviewed for medical necessity each Acthar prescription that it covered. (Cmplt. ¶ 16, ¶ 271.) Acthar is a unique, complex injectable biopharmaceutical product that is approved by the FDA for use in nineteen serious and hard-to-treat rare medical conditions, such as infantile spasms, lupus, multiple sclerosis, nephrotic syndrome, and rheumatoid arthritis. While HCSC labels a 2007 price increase for Acthar "price gouging," HCSC admits that Mallinckrodt's predecessor-in-interest Questcor raised the price to pull Acthar out of, as HCSC describes it, a "financial sinkhole" to "save" the product from being removed from the marketplace. (Cmplt. ¶¶ 7-9.) Thereafter, the price of Acthar has risen at only five percent per year, not counting inflation. (*Id.*)

Saving Acthar was critically important for the small patient population that needs it. Questcor's 2007 price increase was necessary to make manufacturing and selling the injectable specialty therapy viable. Questcor and later Mallinckrodt (whose parent Defendant Mallinckrodt plc acquired Questcor in 2014) made significant investments in medical research into the product's safety and efficacy for existing and new indications as well as educating prescribers about Acthar's FDA-

1 approved indications so the therapy is appropriately prescribed to the patients for whom it is a suitable
2 treatment. Questcor also improved the distribution system for Acthar by shifting to a specialty-
3 pharmaceutical distribution model, which provides greater care, speed, and expertise in ensuring this
4 perishable specialty therapeutic is efficiently delivered to patients who need it urgently. As is typical
5 for specialty pharmaceutical products, Questcor also established a patient support program, or “hub,”
6 that helps patients for whom Acthar has been prescribed submit claims for insurance coverage, appeal
7 denials of coverage, secure financial assistance with co-payment obligations, coordinate home
8 delivery, and provides injection training and support.

9 HCSC attempts to recast Acthar’s turnaround as the result of illegal monopoly, bribery,
10 racketeering, and fraud by Questcor, after it purchased the rights to Acthar in 2001, and later by
11 Mallinckrodt, which Defendant Mallinckrodt plc purchased from Questcor in 2014. In essence,
12 HCSC’s suit seeks to retroactively renegotiate the price it paid over the last eight years for medically
13 necessary prescriptions. Once stripped of HCSC’s incendiary labels, none of the categories of alleged
14 misconduct supports the Complaint’s nine counts under forty states’ laws.

15 HCSC complains about Questcor’s enhancements to the distribution system for Acthar using
16 nefarious phrases like “exclusive” and “vertically integrated operation,” but exclusive distribution and
17 other “vertical” agreements are presumptively procompetitive.

18 HCSC further alleges that Questcor violated 32 states’ antitrust laws when, in June 2013,
19 Questcor acquired the development rights to a synthetic ACTH product called Synacthen Depot
20 (“Synacthen”), which is not FDA approved, and thus secured an illegal monopoly in the “ACTH drug
21 market.” But HCSC’s alleged market definition is legally deficient, and HCSC does not and cannot
22 plead injury resulting from the acquisition. If these claims were not subject to dismissal, the
23 appropriate relevant antitrust market, Synacthen’s realistic prospects for FDA approval, and whether
24 the acquisition in fact injured both competition and HCSC would be significant factual and legal issues
25 in dispute. Questcor acquired rights to Synacthen to continue its sale in various countries outside the
26 United States where it had received approval and also to explore indications for which it might have a
27 potential for FDA-approval for use in the United States. Infantile spasms, for which Acthar is the
28 standard of care, would not be among those indications without a reformulation to remove benzyl

1 alcohol, which the FDA and doctors in the United States likely would be reluctant to administer to
2 infants. Synacthen's viability as a US product proved to be less than initially hoped. This fact has
3 been demonstrated in the real world because three years ago, Mallinckrodt divested its rights to
4 develop and market Synacthen for infantile spasms and nephrotic syndrome in the United States, yet
5 Synacthen is still not FDA approved for any indication, and the sublicensee recently announced that
6 Synacthen's "development is no longer feasible in a timely manner."

7 HCSC also complains that Mallinckrodt has funded programs that help patients insured by
8 HCSC who have been prescribed Acthar pay their co-payments for the therapy. But Mallinckrodt's
9 conduct in regard to those programs was lawful and consistent with relevant industry guidance, and
10 HCSC fails to state a claim otherwise; in any event, because the alleged misconduct has been well
11 known since 2013, HCSC's claims are time barred. Under these claims, Mallinckrodt's intent to
12 operate in compliance with applicable laws, and the effect of co-payment assistance on utilization
13 would be issues in dispute.

14 Similarly, HCSC attempts to label Questcor's and Mallinckrodt's respective significant
15 investments in medical research and education from 2011 to the present as "bribes" paid to doctors in
16 exchange for writing Acthar prescriptions. But HCSC pleads no facts supporting that
17 mischaracterization. If these claims were not subject to dismissal, the parties would dispute whether
18 payments to doctors were legitimate compensation for services, whether prescriptions written by the
19 subject doctors were medically appropriate, and HCSC's policies and practices concerning coverage
20 of Acthar.

21 HCSC also alleges that Questcor promoted Acthar for an off-label dosing regimen to treat
22 multiple sclerosis. Doctors are, of course, free to prescribe off label. HCSC fails to identify with the
23 requisite particularity any unlawful promotional activity by anyone at Questcor or Mallinckrodt to any
24 particular doctor, let alone a connection between any such alleged promotion, reliance thereon, and
25 reimbursement by HCSC, which mandates dismissal of HCSC's fraud-based claims. If these claims
26 were not subject to dismissal, promotional activity by Questcor and Mallinckrodt for Acthar, and
27 HCSC's policies and practices concerning coverage of Acthar would be issues in dispute.

1 **IV. AGREED UPON AND DISPUTED CASE MANAGEMENT ISSUES**

2 A hearing on Defendant’s demurrer and motion to strike is scheduled for August 5, 2020, at 3
3 PM in Department 19. The parties propose a staged approach to discovery under which the they begin
4 with a four-month period for document discovery and then reconvene for a case management
5 conference in November, when more is known about the scope of the case and the impact of the
6 pandemic on the pace of litigation, to schedule subsequent stages of the case.

7 In the event the Court is inclined to set a more complete case schedule at this time, the parties
8 jointly and tentatively propose as follows:

9

Date	Event
June 30, 2021	Fact discovery deadline
July 2021	Parties to conduct mediation at a time and place to be determined
September 22, 2021	Plaintiff to produce expert reports
November 19, 2021	Defendants to produce expert reports
January 20, 2022	Summary judgment or summary adjudication deadline
TBD	Trial

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16 This Court has ordered that it “expects the parties to engage in focused, limited discovery”
17 prior to a hearing on Defendant’s demurrer and motion to strike. May 18, 2020 Case Management
18 Order at 2. To that end, the parties are discussing a preliminary exchange of documents. Under that
19 exchange, Mallinckrodt will provide to HCSC documents that Mallinckrodt has produced in
20 government investigations and other civil actions relating to the conduct alleged in the Complaint,
21 along with an index of custodians and search terms. HCSC will provide to Mallinckrodt its claims
22 data and purchase data, and will meet and confer with Mallinckrodt concerning whether there are other
23 documents appropriate for early exchange. Specifically, Mallinckrodt requested that two other
24 categories of documents be part of this initial exchange: (a) pre-authorization claim forms for Acthar
25 prescriptions and (b) the allocation between HCSC and Medicare of the cost of Acthar prescriptions
26 for members of HCSC’s Medicare Part D plans. HCSC, however, wants to meet and confer over any
27 such productions. HCSC will also provide Mallinckrodt with requested information so that they can
28

1 begin a discussion regarding the designation of document custodians for HCSC's collection and
2 production of custodial documents.

3 The parties agree that they will submit for entry by the Court a Protective Order, and
4 stipulations concerning electronically stored information ("ESI") and expert discovery. Should the
5 parties not agree on certain aspects of these orders, they will meet and confer to resolve their
6 differences and, if they cannot, they will abide by the Court's procedures to resolve their differences.

7 The parties have discussed the use of alternative dispute resolution ("ADR") and mediation
8 services, as provided for the Court's May 21, 2020 Notice of Reassignment. The parties have
9 proposed provision for private mediation as part of their proposed case schedule.

10 A. Plaintiff's Position on Additional Case Management Issues and Discovery

11 HCSC believes that periodic status conferences will help with the progress of this litigation.
12 HCSC proposes that the Court conduct bi-monthly status conferences, and that the parties submit a
13 statement outlining any outstanding issues one week before any scheduled conference. In light of the
14 COVID-19 pandemic, which has impacted the Court and parties alike, HCSC proposes to conduct
15 status conferences by video conference or some other method convenient to the Court. Based on
16 Defendants' proposal, described below, to conduct "substantial" discovery against HCSC when the
17 most germane issues with respect to HCSC will be the straight-forward matters of the nature and
18 extent HCSC's purchases, HCSC anticipates that periodic conferences will assist the parties in
19 conducting efficient and focused discovery.

20 B. Defendants' Position on Additional Case Management Issues and Discovery

21 Mallinckrodt urges the Court to consider strongly accepting the parties' proposal to stage
22 discovery. HCSC challenges five categories of conduct alleging nine separate counts under the laws
23 of over forty different states, and it places at issue all Acthar prescriptions that HCSC covered back to
24 2011. As previewed above, there are several grounds on which to dismiss and/or strike the Complaint
25 in its entirety or to substantially narrow the scope of the case by eliminating entire categories of
26 alleged misconduct or narrowing the relevant period. Courts addressing similar claims by other
27 Acthar payors have substantially narrowed or dismissed the actions on the pleadings.¹

28 ¹ See *MSP Recovery Claims, Series LLC, et al. v. Mallinckrodt ARD Inc.*, No. 3:20-cv-50056 (N.D.
Ill. Mar. 23, 2020) (dismissing, with leave to amend, complaint for failure to plead standing);

1 Once the scope of the case is established, discovery will not be a one-way street. Many of
2 HCSC's claims are fraud-based claims that, on a prescription-by-prescription basis, raise questions
3 about what was said, whether it was relied on, and whether the statement or other conduct caused
4 HCSC to cover an Acthar prescription that it otherwise would not have covered. HCSC will also have
5 discoverable admissions regarding the alternative treatments to Acthar for the various conditions for
6 which it is used, and those admissions will bear on the antitrust claims. In addition, discovery into
7 HCSC's actual or constructive knowledge of its claims could give rise to statute of limitations
8 defenses given that it complains about very old conduct.

9 With respect to HCSC's proposal to schedule regular conferences with the Court, Mallinckrodt
10 draws some confidence from the parties' ability to cooperate informally to date in this action, and it
11 believes that they will be able to informally resolve many discovery disputes as they arise.
12 Mallinckrodt therefore does not think the Court should dedicate some of its limited resources to the
13 resolution of disputes that have not yet arisen.

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22 *Humana Inc. v. Mallinckrodt ARD LLC*, No. CV 19-06926 (C.D. Cal. March 9, 2020) (“*Humana*
23 *Order*”) (dismissing, with leave to amend, antitrust and tortious interference—but allowing RICO,
24 consumer protection, and common law—claims); *Acument Global Technologies, Inc. v.*
25 *Mallinckrodt ARD, Inc.*, No. CT-2275-19 (Cir. Ct. Shelby Cty. Tenn. Feb. 21, 2020) (dismissing
26 fraud and consumer protection, but allowing antitrust and unjust enrichment, claims); *Washington*
27 *Cty. Bd. of Educ. v. Mallinckrodt ARD, Inc.*, ___ F. Supp. 3d ___, No. CV JKB-19-1854, 2020 WL
28 43016 (D. Md. Jan. 3, 2020) (dismissing action by rejecting fraud and consumer-protection claims);
City of Rockford v. Mallinckrodt ARD, Inc., 360 F. Supp. 3d 730 (N.D. Ill. 2019) (dismissing RICO
and common-law, but allowing antitrust, claims); *but see Steamfitters Local Union No. 420 v.*
Mallinckrodt ARD, LLC, No. 19-cv-03047 (E.D. Pa. Dec. 19, 2019) (denying, without an opinion,
motion to dismiss RICO, consumer-protection, and common-law claims); *Int’l Union of Operating*
Engineers Local 542 v. Mallinckrodt ARD, LLC, No. 2018-14059 (Pa. Commw. Ct., Montgomery
Cty. Jan. 8, 2019) (denying preliminary objections to antitrust-related theories of harm brought under
consumer protection statute)

1
2 Dated: June 16, 2020

Respectfully submitted:

3
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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**PLAINTIFF HEALTH CARE SERVICE
CORP.'S OPPOSITION TO
DEFENDANTS MALLINCKRODT ARD
LLC AND MALLINCKRODT PLC'S
DEMURRER AND MOTION TO
STRIKE**

Judge: Hon. Stephen Kaus
Location: Dept. 19
Hearing: August 5, 2020; 3:00 p.m.

Complaint Filed: February 27, 2020

Trial Date: Not Set

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1 **I. INTRODUCTION**

2 Plaintiff Health Care Service Corporation (“HCSC”) respectfully submits this opposition to the
 3 demurrer and motion to strike filed by Defendants Mallinckrodt ARD LLC and Mallinckrodt plc
 4 (together, “Mallinckrodt”). HCSC’s claims relate to its payments for H.P. Acthar Gel (“Acthar”), a
 5 prescription drug used to treat infant seizures. Although Acthar had been available in the United States
 6 since 1952, Acthar has seen some of the largest price hikes in the history of medicine, increasing nearly
 7 ten thousand-fold from 2001 to 2018. To pull this off, Mallinckrodt acquired the rights to Acthar, and
 8 subsequently (i) eliminated competition in the market for Acthar through an exclusive distribution
 9 agreement; (ii) completed a “catch and kill” acquisition of Synacthen, Acthar’s only biologically-
 10 equivalent competitor; and (iii) created artificial demand for Acthar by illegally subsidizing patient co-
 11 payments, promoting off-label use of the drug, and bribing physicians to prescribe it. As a result of
 12 Mallinckrodt’s anticompetitive and fraudulent conduct, HCSC has paid millions of dollars more for
 13 Acthar than it otherwise would have.

14 Mallinckrodt makes a hodge-podge of arguments as to why HCSC’s allegations are legally
 15 insufficient, many of which have been rejected by other courts that have sustained substantially identical
 16 claims. *See City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 757 (N.D. Ill. 2019)
 17 (“defendants’ conduct was anticompetitive under the Seventh Circuit’s broad definition of exclusionary,
 18 predatory, or anticompetitive. ... Rockford alleged that defendants conspired to price-fix and prevent
 19 competitors from entering the market, implemented through a joint-effort (the ASAP) that allowed
 20 Mallinckrodt to unlawfully acquire the rights to Synacthen”) (sustaining claims under Section 1 and 2
 21 of the Sherman Act); *Humana Inc. v. Mallinckrodt ARD, LLC*, 2020 U.S. Dist. LEXIS 101378, at **7–19
 22 (C.D. Cal. Mar. 9, 2020). (“Here, there is more than a conclusory allegation as to the other parties’
 23 involvement in, and knowledge of, the alleged fraud. There are specific allegations that CDF and the
 24 prescribing doctors acted in ways unrelated to ordinary business aims.”) (sustaining RICO, unfair
 25 competition, consumer fraud and deceptive trade practices, insurance fraud, and unjust enrichment
 26 claims).

27 HCSC alleges claims for violations of New Jersey’s Racketeer Influenced Corrupt Organizations
 28 Act (Counts I & II), antitrust violations (Counts III & IV), unfair and deceptive trade practices (Count

V), fraud (Count VI), insurance fraud (Count VII), tortious interference with contract (Count VIII), and unjust enrichment (Count IX). Mallinckrodt's demurrer to these causes of action should be overruled for the reasons set forth below. Similarly, Mallinckrodt's motion to strike—which improperly asks the Court to strike relevant allegations that they contend do not constitute a cause of action—should be denied, as “[a] motion to strike does not lie to attack a complaint for insufficiency of allegations to justify relief; that is a ground for general demurrer.” *Pierson v. Sharp Mem’l Hosp.*, 216 Cal. App. 3d 340, 342-43 (1989).

II. FACTUAL ALLEGATIONS

Acthar is an adrenocorticotrophic hormone (“ACTH”) drug manufactured from the pituitary gland of pigs. Complaint, ¶¶ 56–57.¹ Approved for marketing in the United States since 1952, Acthar is an anti-inflammatory that can be used to treat multiple conditions including sarcoidosis, multiple sclerosis, and rheumatoid arthritis in limited clinical settings. ¶¶ 58–67. Aside from use to treat a rare epileptic disorder in infants, however, there is almost no clinical evidence to support its use over much cheaper alternatives. *Id.* Mallinckrodt's predecessor, Questcor Pharmaceuticals, acquired the right to produce Acthar in 2001 for \$100,000 plus modest royalties. ¶¶ 7, 69. At that time, Acthar was priced at \$40 per vial, but Mallinckrodt drastically increased Acthar's price over the course of a few years. ¶¶ 8, 70–71. By 2018, a vial of Acthar cost \$38,892. ¶¶ 8, 72. In order to make this dramatic price hike, Mallinckrodt engaged in a five-part scheme.

First, Mallinckrodt entered into an exclusive distribution arrangement with Express Scripts Holding Company and its subsidiaries. ¶ 11. This arrangement had the effect of foreclosing competition in the distribution market for Acthar which allowed Mallinckrodt to abusively price the drug. ¶¶ 76–85. This was carried out through the Acthar Support and Access Program (“ASAP”), a vehicle that Mallinckrodt used to further raise prices and stifle competition. ¶¶ 106-112.

Second, Mallinckrodt increased and then maintained artificially high demand for Acthar by marketing it as “free” to patients by using a phony charitable foundation to pay patient co-payments,

¹ All “¶” references herein are to HCSC's Complaint, filed on February 27, 2020. “MPA” refers to The Defendant Mallinckrodt Entities Memorandum In Support of Demurrer and Motion to Strike, dated May 20, 2020, and filed in this action on May 28, 2020.

1 while sticking their insurers with tens or hundreds of thousands of dollars in costs. ¶ 12, 89–119 (the
2 “CDF Co-Pay Scheme”). “In other words, the co-payment subsidies were bribes to patients and a
3 vehicle through which Mallinckrodt could persuade physicians that the astronomical price of the drug
4 should not be a barrier to prescribing it.” ¶ 12. Mallinckrodt accomplished this fraud by conspiring with
5 the Chronic Disease Fund (“CDF”), an existing charity, to create disease- and symptom-specific funds
6 whose only qualifying drug was Acthar and whose sole source of funds was Mallinckrodt. *Id.* The Co-
7 Pay Scheme violated anti-kickback statutes and the federal False Claims Act. *E.g.*, ¶ 191; *see also* ¶¶ 30–
8 43 (regulatory framework).

9 *Third*, Mallinckrodt further expanded the market with aggressive promotion of an unproven and
10 ineffective dosing regimen. ¶¶ 13, 121–45. Acthar’s label instruct patients to inject the drug as part of a
11 daily dosing regimen to be used for two to three weeks at a time. ¶ 13. This regimen is extremely
12 expensive because it requires use of multiple vials of the drug and increases the risk of side effects in
13 patients. *Id.* To solve these problems, Mallinckrodt developed a different dosing regimen that only
14 required patients to use Acthar for five days, even though there was no clinical evidence that the five-
15 day dosing regimen was effective. *Id.* This dosing regimen was not FDA approved or indicated on the
16 Acthar label. *Id.* This dosing protocol had a two-fold effect: (1) patients reported fewer side effects,
17 lending credibility to Mallinckrodt’s unsupported claim of superior tolerability for Acthar when
18 compared to steroids; and (2) the price seemed affordable when compared with the cost of
19 administering the drug according to the label’s instructions. *Id.* These off-label promotion efforts
20 violated FDA regulations. *See* ¶¶ 44–55.

21 *Fourth*, Mallinckrodt simultaneously maintained artificially high demand through a pervasive
22 scheme to pay doctors to prescribe Acthar. ¶¶ 14, 149–160. These payments were necessary because
23 Acthar is an antiquated and expensive drug that requires refrigeration and injection, and it is not the
24 first-line treatment for most of its indicated conditions. ¶ 14. Instead, much cheaper and more effective
25 treatments are recommended. *Id.* Under the guise of “education” and “marketing,” Mallinckrodt paid
26 millions of dollars to thousands of doctors, and particularly large sums to a smaller number of doctors
27 who then prescribed a disproportionate amount of Acthar. ¶¶ 14, 159–60. Mallinckrodt paid more than
28 \$15 million to the United States Department of Justice (“DOJ”) to settle a False Claims Act case arising

1 from this conduct. ¶ 161.

2 *Finally*, Mallinckrodt eliminated competition by acquiring the exclusive right to sell in the U.S.
 3 Acthar’s much cheaper synthetic equivalent ACTH, Synacthen Depot (“Synacthen”). ¶¶ 15, 162–173.
 4 To do so, Mallinckrodt substantially outbid competing bidders for the Synacthen rights, but rather than
 5 trying to commercialize the drug, it shelved those rights to protect its Acthar monopoly. ¶¶ 15, 165–
 6 172. Mallinckrodt paid \$100 million to settle the Federal Trade Commission’s (“FTC”) claim that its
 7 acquisition of the rights to Synacthen was anticompetitive and illegal. ¶ 175.

8 Because of Mallinckrodt’s scheme, HCSC has overpaid for Acthar. ¶ 16. In addition to
 9 Mallinckrodt’s competition-eliminating conduct that allowed Mallinckrodt to maintain artificially high
 10 prices for Acthar (¶¶ 204–15), HCSC was defrauded when it paid for Acthar. In making its decision to
 11 pay for Acthar therapy for its beneficiaries, HCSC relied on representations made by, or caused to be
 12 made by, Mallinckrodt, that Mallinckrodt had not violated laws prohibiting the CDF Co-Pay Scheme,
 13 the off-label promotion efforts, and the physician kickbacks. *E.g.*, ¶¶ 220, 228, 239, 259–63, 267–78.
 14 Mallinckrodt actively concealed the illegal scheme and its underlying acts through false or misleading
 15 statements. *E.g.*, ¶¶ 177–79. HCSC was not aware of and could not have discovered Mallinckrodt’s
 16 illegal conduct until the FTC and the DOJ brought that illegal conduct to light through their
 17 enforcement efforts in 2017 (FTC) and 2019 (DOJ). ¶¶ 161, 175, 180.

18 **III. LEGAL STANDARD ON DEMURRER**

19 “As a general rule in testing a pleading against a demurrer the facts alleged in the pleading are
 20 deemed to be true, however improbable they may be.” *Del E. Webb Corp. v. Structural Materials Co.*, 123
 21 Cal.App.3d 593, 604 (1981). “[A]ll material facts pleaded in the complaint and those that arise by
 22 reasonable implication . . . are deemed admitted by the demurring party. The complaint must be
 23 construed liberally by drawing reasonable inferences from the facts pleaded.” *Rodas v. Spiegel*, 87
 24 Cal.App.4th 513, 517 (2001) (citation omitted). “A complaint’s allegations are construed liberally in
 25 favor of the pleader.” *Ferrick v. Santa Clara Univ.*, 231 Cal. App. 4th 1337, 1341 (2014); Cal. Code Civ.
 26 Proc. § 452.

27 Mallinckrodt contends “plausibility” is the standard that governs HCSC’s allegations. MPA at
 28 17, 24, 25, 31. This is error. California pleading practice does not require that allegations be “plausible.”

1 *See, e.g., Del E. Webb Corp.*, 123 Cal. App. 3d at 604 (“As a general rule in testing a pleading against a
 2 demurrer the facts alleged in the pleading are deemed to be true, however improbable they may be.”);
 3 *see also Mekkebe v. Westin Hotel*, 2015 Cal. Super. LEXIS 12481, *6 (“It is difficult to conceive of how that
 4 could be so but generally demurrers at least in state court do not test for plausibility.”); Weil & Brown,
 5 et al., CALIFORNIA PRACTICE GUIDE: CIVIL PROCEDURE BEFORE TRIAL ¶ 7:44 (2015).

6 **IV. ARGUMENT**

7 **A. HCSC Sufficiently Alleges Violations of State Antitrust Law.**

8 Central to its antitrust theories, HCSC alleges that Mallinckrodt overpaid for and then shelved
 9 the exclusive licensing rights to Synacthen, the only potential competition to Acthar in the United States
 10 ACTH market. ¶¶ 162–176. Mallinckrodt does not dispute that this conduct amounts to an unlawful
 11 restraint of trade or monopoly in violation of the antitrust laws. Indeed, in *City of Rockford*, the court
 12 found that “[o]ne can plausibly infer that the Synacthen Acquisition and Mallinckrodt’s immediate
 13 ‘shelving’ of Synacthen had no legitimate business justification and resulted in the maintenance and
 14 entrenchment of Mallinckrodt’s monopoly.” *City of Rockford*, 360 F. Supp. 3d at 757. HCSC alleges that
 15 Mallinckrodt entered into an exclusive distribution agreement with Express Scripts to maintain
 16 Mallinckrodt’s monopoly in the ACTH market. ¶¶ 11, 76–85. This arrangement foreclosed competition
 17 in the ACTH market to the detriment of consumers. This conduct is part of Mallinckrodt’s scheme to
 18 monopolize the ACTH market in violation of state law equivalents to Section 1 and 2 of the Sherman
 19 Act. *City of Rockford*, 360 F. Supp. 3d at 730 (“Rockford alleges two anticompetitive understandings—
 20 the exclusive dealing arrangement and the Synacthen Acquisition—that together form the basis of their
 21 § 1 claims.”).

22 Mallinckrodt attacks HCSC’s theories by arguing (i) ACTH is not a relevant antitrust market,
 23 (ii) that HCSC was uninjured, and (iii) HCSC’s exclusive distribution allegations state no claim.
 24 Mallinckrodt is wrong on all points.

25 **1. Mallinckrodt’s Conduct Impacted a Relevant Antitrust Market.**

26 Mallinckrodt argues that HCSC has failed to allege a proper antitrust market because “Acthar
 27 represents 100% of the [ACTH] market” and HCSC also alleges that non-ACTH drugs are *medical*
 28 substitutes for the treatment of many Acthar indications. MPA at 30–31. Mallinckrodt’s arguments

1 ignore a great body of relevant case law that define relevant antitrust markets in the pharmaceutical
2 context as a brand drug and its biological equivalent.

3 A “relevant market” is properly defined as consisting of “commodities reasonably
4 interchangeable by consumers for the same purposes.” *United States v. E.I. du Pont de Nemours & Co.*, 351
5 U.S. 377, 395 (1956). “The Supreme Court has held that a properly constituted market may indeed be
6 comprised of a single product ... and lower courts across the country have on numerous occasions
7 ruled that both a brand-name drug and its generic analogs can fall within the bounds of a relevant
8 market.” *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F.Supp.2d 367, 388 (D. Mass. 2013) (collecting
9 cases showing the market consists of a brand drug and a generic substitute). In other words, ACTH and
10 its biological equivalents (e.g., Synacthen) is a proper antitrust market.

11 Here, HCSC alleges that there are no economic substitutes for Acthar, other than a biologically
12 equivalent ACTH. ¶ 184 (“Acthar does not exhibit significant, positive cross-elasticity of demand
13 regarding price with any other product.”); *see also* ¶¶ 182–183, 185, 191 (“No other ACTH product
14 (except Synacthen or AB-rate[d] generic versions of Acthar) will, or would, take away sufficient sales
15 from this drug to prevent Mallinckrodt from raising or maintaining the price of its product above levels
16 that would prevail in a competitive market.”). These allegations give boundaries to the market
17 commonly accepted in pharmaceutical antitrust litigation: it is Acthar and its biological equivalent, as
18 no other drug could take away sales anywhere close to as much as a generic could have done. *See In re*
19 *Cipro Cases I & II*, 61 Cal. 4th 116, 157 (2015) (relevant market under the Cartwright Act is a brand drug
20 and its generic substitute); *Nexium*, 968 F.Supp.2d at 387–88 (market defined by “cross-elasticity of
21 demand for the product in question — the extent to which purchasers will accept substitute products
22 in instances of price fluctuation and other changes”).

23 Mallinckrodt posits that some other treatments may offer similar therapeutic relief. MPA at 31.
24 What is missing from this analysis is that the other treatment are **not** biological equivalents. *Cf. United*
25 *Food & Commer. Workers Local 1776 v. Teikoku Pharma USA*, 296 F.Supp.3d 1142, 1172 (N.D. Cal.
26 2017) (“something *more* than mere therapeutic equivalency is required to define the relevant antitrust
27 product market.”). In any event, the definition of the market at issue is a question of fact, not properly
28 resolved on a demurrer. *See In re Loestrin 24 Antitrust Litig.*, 261 F.Supp.3d 307, 326 (D.R.I. 2017) (“courts

generally treat this fact-intensive issue as one to be decided on a motion for summary judgment (if no genuine issue of material fact exists) or at trial.”); *Nexium*, 968 F.Supp.2d at 388 n.19 (“the reasonable interchangeability of brand Nexium with other drugs” is “a factually intensive determination [that] is better left for resolution by a jury”).

Mallinckrodt points to the *Humana* decision where the court dismissed with leave to amend antitrust claims based on an ACTH-only market. MPA at 31. However, the *Humana* court did not consider the *economic* substitutability of other products with Acthar, did not address the line of cases cited above, and did not consider well-pled allegations of biological equivalents and relative cross-elasticity, which demonstrate that only biological equivalents could take significant market share away from Acthar. *See Humana Inc. v. Mallinckrodt ARD, LLC*, No. CV-19-06296, 2020 U.S. Dist. LEXIS 101378, at **7–19 (C.D. Cal. Mar. 9, 2020).

2. The Synacthen Acquisition Caused HCSC Injury.

Mallinckrodt contends that HCSC “fails to offer ‘specific facts’ making th[e] connection between the [Synacthen acquisition] and injury plausible[.]” MPA at 31. This argument ignores HCSC’s allegations. HCSC alleges that three firms negotiated for the rights to license Synacthen, a lower-priced Acthar alternative. ¶ 165; *see also* ¶ 174. The firms planned to develop Synacthen to compete with, and price below, Acthar. ¶ 166. The firms had the requisite expertise, financing, business, and regulatory plans to develop Synacthen for the United States market. *Id.*; *see also* ¶ 167. Had Mallinckrodt not swept in at the eleventh hour with an outsize bid, another company would have “begun manufacturing Synacthen shortly after acquiring the license from Novartis and launched the product earlier than Mallinckrodt.” ¶ 202. This course of conduct enabled Mallinckrodt to prevent entry of Synacthen into the United States market, raise the price of Acthar, and maintain its monopoly power in the ACTH market. ¶ 201; *see also* ¶ 203. And “but for Mallinckrodt’s monopolistic conduct, including its acquisition of Synacthen, HCSC would have benefitted from increased competition in the market for ACTH drugs and would have either paid lower prices for Acthar or steered its members to lower priced Synacthen.” ¶ 214. These allegations clearly allege that Mallinckrodt’s acquisition of Synacthen and its subsequent shelving caused HCSC injury. No more is needed.

1 Mallinckrodt’s contention that HCSC failed to allege “when Synacthen would have gone
 2 through the extensive clinical trials to establish its safety and efficacy necessary to gain FDA approval
 3 an[d] enter the market” and “which indications FDA would approve it for” (MPA at 32) ignores HCSC’s
 4 allegations. HCSC alleges the when (§§ 202, 203, 205), and it is reasonable to infer that another company
 5 would have sought approval of Synacthen for the same indications as Acthar. *See* ¶ 162 (“In Europe,
 6 Canada, and other parts of the world, doctors treat patients with Synacthen for the same conditions
 7 that are treated with Acthar in the U.S.”); ¶ 163 (“Questcor itself considered the drugs so similar that it
 8 submitted Synacthen information to support its application to the FDA to expand the label indications
 9 for Acthar.”); *Rodas v. Spiegel*, 87 Cal.App.4th 513, 517 (2001) (when ruling on a demurrer, courts are to
 10 construe complaints “liberally by drawing reasonable inferences from the facts pleaded.”)²

11 Moreover, HCSC need not allege the specific mechanisms through which a hypothetical
 12 Synacthen licensor would have sought FDA approval, or what the FDA would have done, if
 13 Mallinckrodt had not illegally overpaid for the rights to sell the drug. This case presents similar
 14 circumstances as *Tamfilis v. Allergan, Inc.*, 157 F.Supp.3d 853 (C.D. Cal. 2015). In *Tamfilis*, as here,
 15 defendant monopolist acquired the exclusive rights to market a competing drug in the United States,
 16 although the drug had not yet been approved to be marketed in the United States. *Id.* at 856–58. And
 17 like Synacthen, the competing drug had already received foreign regulatory approval and was marketed
 18 abroad. *Id.* at 858. The hypothetical potential market entrant, as here, had “extensive experience selling
 19 drugs throughout the world[.]” *Id.* at 866. Against this background, the court rejected defendant’s
 20 argument that plaintiffs failed to allege causation because they “allege nothing at all regarding [potential
 21 entrant’s] ability to obtain an approved manufacturing plant . . . obtain FDA approval, market and sell
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26 ² Mallinckrodt moves to strike HCSC’s claimed overcharges “starting in 2011 or sometime prior to
 27 2014.” MPA at 33. This argument ignores that HCSC alleges claims based on Mallinckrodt’s conduct
 28 well before 2011, as well as the inappropriate use of a motion to strike as a “line item veto” of otherwise
 relevant allegations as discussed in Section IV.F. below. The scope and nature of HCSC’s damages are
 not properly resolved on pleadings motions.

1 [the competing drug] in the U.S., or any other steps to overcome the high barrier to entry.” *Id.* at 865–
 2 68 (quotations omitted). This Court should do the same.³

3 3. HCSC’s Allegations of Exclusive Distribution Are Actionable.

4 Mallinckrodt argues that one aspect of HCSC’s allegations—that HCSC was able to maintain
 5 inflated prices through an exclusive distribution agreement through Express Scripts—fails to state a
 6 claim. MPA at 17-20. Mallinckrodt misconstrues HCSC’s allegations, which do not exist in a vacuum.
 7 Mallinckrodt improperly considers the exclusive distribution agreements in isolation, which is fatal to
 8 its challenge because “in the antitrust context, the ‘character and effect of a conspiracy are not to be
 9 judged by dismembering it and viewing its separate parts, but only by looking at it as a whole.’ ” *Costco*
 10 *Wholesale Corp. v. Maleng*, 522 F.3d 874, 886 (9th Cir. 2008) (quoting *Continental Ore Co. v. Union Carbide*
 11 *& Carbon Corp.*, 370 U.S. 690, 699 (1962)). A wholistic view is also applied to monopolization claims.
 12 *See Med. Res. Corp. v. Ethicon Inc.*, 2006 U.S. Dist. LEXIS 12845, a *17 (C.D. Cal. Feb. 2, 2006) (in
 13 determining willfulness, “what is dispositive is the overall effect of the conduct”); *Mishawaka v. Am.*
 14 *Elec. Power Co.*, 616 F.2d 976, 986 (7th Cir. 1980) (“[Defendant] would have us consider each separate
 15 aspect of its conduct separately and in a vacuum. If we did, we might agree with the utility that no one
 16 aspect standing alone is illegal. It is the mix of the various ingredients of utility behavior in a monopoly
 17 broth that produces the unsavory flavor.”).

18 The *Continental Ore* principle has equal application here: While exclusive distribution
 19 arrangements are “not illegal **in themselves**,” they can run afoul of antitrust laws as “an improper
 20 means of maintaining a monopoly.” *See United States v. Dentsply Int’l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005)
 21 (emphasis added). Such arrangements violate the antitrust laws when they “foreclose competition in a
 22

23 ³ Mallinckrodt’s cases concern complaints that failed altogether to allege competing products could be
 24 brought to market, because regulatory approval was lacking either on the face of the complaint or on
 25 summary judgment. *Andrx Pharms., Inc. v. Biovail Corp. Int’l*, 256 F.3d 799, 807 (D.C. Cir. 2001); *Brotech*
 26 *Corp. v. White Eagle Int’l Techs. Group, Inc.*, 2004 U.S. Dist. LEXIS 11552, at *21 (E.D. Pa. June 21, 2004);
 27 *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 852, 862 (D.C. Cir. 2008); *Sunbeam Television Corp. v. Nielsen Media*
 28 *Research, Inc.*, 711 F.3d 1264, 1273 (11th Cir. 2013). Here HCSC alleges that the potential market entrants
 were prepared to bring Synacthen to market, anticipated FDA approval, and that FDA approval would
 have happened in the absence of Mallinckrodt’s conduct. Additionally, “*Andrx* requires neither probable
 approval nor specific facts about the plaintiff’s approval process” to show intent and preparedness.
Biocad JSC v. F. Hoffmann-La Roche, 942 F.3d 88, 104 (2d Cir. 2019) (Katzmann, J., concurring).

1 substantial share of the line of commerce affected.” *Allied Orthopedic Appliances Inc. v. Tyco Health Care*
 2 *Group LP*, 592 F.3d 991, 996 (9th Cir. 2010). In other words, the arrangements are unlawful when they
 3 “harm the competitive process, and thereby harm consumers.” *McWane, Inc. v. FTC*, 783 F.3d 814, 835–
 4 36 (11th Cir. 2015).

5 HCSC sufficiently alleges that the challenged arrangement has completely foreclosed
 6 competition in the ACTH market.⁴ The exclusive arrangement foreclosed other distributors from
 7 competing with Express Scripts, meaning there is no competition for the downstream sales to
 8 consumers. By engaging with only Express Scripts, Mallinckrodt has restricted patient access to Acthar
 9 and “eliminat[ed] other distributors from negotiating for lower prices for Acthar.” *Rockford*, 360
 10 F.Supp.3d at 744 (determining that plaintiffs sufficiently allege competitive harm flowing from
 11 Mallinckrodt’s exclusive dealing arrangement). Here, as in *Rockford*, “Express Scripts had no interest in
 12 lowering the price for Acthar because it was making money off all aspects of its exclusive arrangement
 13 with the manufacturer.” *Id.* at 744–45. The arrangement “thus allowed Mallinckrodt to maintain its
 14 dominant monopoly power in the ACTH drug market, maintain prices at artificially high levels, and
 15 exclude less expensive competitive products from the ACTH drug market.” *Id.* at 755.

16 Mallinckrodt argues that an exclusive distribution arrangement “provides no monopolistic
 17 benefit to [a monopolist] that it does not already enjoy.” MPA at 19, quoting *E&L Consult., Ltd. v.*
 18 *Doman Indus. Ltd.*, 472 F.3d 23, 29 (2nd Cir. 2006). However, reliance on *E&L* is misplaced. Central to
 19 the court’s holding in *E&L* was the fact that the manufacturer in that case could have distributed the
 20 product itself and did not have to rely on the intermediary. *Id.* at 29. HCSC’s complaint does not suggest
 21 that Mallinckrodt had the ability to act as its own distributor; Mallinckrodt needed Express Scripts so
 22 that it could sell Acthar without interference from competing distributors who might
 23 impede Mallinckrodt’s ability to control Acthar’s price. And in *E&L*, unlike here, “nothing in the
 24 complaint suggest[ed] that th[e] agreement result[d] in . . . [an] effect on competition.” *Id.* at 29; *see also*
 25 *City of Rockford v. Mallinckrodt ARD, Inc.*, No. 17 C 50107, 2019 U.S. Dist. LEXIS 103885, at *8 (N.D.

27 ⁴ To the extent that cases hold that the anticompetitive effect must be on competition in the *interbrand*
 28 market (*see* MPA at 19), the *interbrand* requirement is not applicable here as Acthar is currently the only
 brand in the United States ACTH market, which, as discussed above, is a proper antitrust market.

1 Ill. May 3, 2019) (rejecting same *Eck*-based argument that Mallinckrodt makes here).⁵

2 **B. Mallinckrodt Has Violated New Jersey's RICO Act.**

3 Mallinckrodt does not for these purposes dispute that HCSC sufficiently alleges claims under
4 New Jersey's Racketeer Influenced and Corrupt Organizations Act ("RICO"), but instead attacks only
5 certain categories of conduct. Mallinckrodt's only challenge to the RICO claims is an argument that the
6 CDF Co-Payment Scheme does not qualify as commercial bribery. MPA at 20–21. Separately,
7 Mallinckrodt argues HCSC has not alleged kickbacks to Prescribing Doctors were unlawful. MPA at
8 24-27. Both of these contentions lack merit.

9 "The gravamen of a RICO violation . . . is the involvement in the affairs of an enterprise through
10 a pattern of racketeering activity." *State v. Ball*, 141 N.J. 142, 155, 661 A.2d 251, 257 (1995). New Jersey
11 defines "racketeering activity" broadly to include, among other things, "any conduct defined as
12 'racketeering activity' under Title 18, U.S.C. § 1961(1)(A), (B) and (D)." N.J. Stat. § 2C:41-1(a). In turn,
13 18 U.S.C. § 1961 defines "racketeering activity" to include acts indictable under 18 U.S.C. §§ 1341 (mail
14 fraud), 1343 (wire fraud), and 1952 (use of interstate facilities to conduct unlawful activity). The
15 "enterprise" alleged by Plaintiffs includes the CDF charity and Mallinckrodt's agents, such as
16 "Prescribing Physicians" who issued Acthar prescriptions in exchange for bribes and kickbacks and
17 made false representations of compliance with federal laws. ¶¶ 149-157, 220. HCSC alleges that
18 Mallinckrodt engaged in "a pattern of racketeering activity . . . including acts indictable under 18 U.S.C.
19 §§ 1341 (mail fraud), 1343 (wire fraud), and 1952 (use of interstate facilities to conduct unlawful activity),
20 and state bribery statutes[.]" ¶ 223 (emphasis added); *see also* ¶¶ 209, 220, 225, 237.

21 Several courts have already held that the scheme alleged by HCSC here violates RICO because
22 the Acthar Enterprise increased sales of Acthar through bribes, kickbacks, and false representations of
23

24 ⁵ Mallinckrodt's argument that "HCSC's allegations amount to nothing more than that CuraScript was
25 a consignment seller" (MPA at 19) is unsupported by the facts and the law. *Shasta Douglas*, cited by
26 Mallinckrodt, shows "it is lawful for a consignor selling through a consignee to fix the price at which
27 he authorizes the consignee to sell the goods of the consignor." *Shasta Douglas Oil Co. v. Work*, 212 Cal.
28 App. 2d 618, 622 (1963). *Wilke & Holzheiser, Inc. v. Dep't of Alcoholic Beverage Control*, 65 Cal. 2d 349, 366
n.13 (1966) observed that any retail outlets or consignment by a manufacturer is "subject of course to
the antitrust laws." Neither case addresses the circumstance here where a monopolist has used an
exclusive distribution agreement to suppress competition in the relevant market.

1 compliance with laws governing prescription. *See, e.g., Humana*, 2020 U.S. Dist. LEXIS 101378, at **19–
 2 37 (denying motion to dismiss RICO claims based on Mallinckrodt’s scheme); *id.* at *38 (allegations that
 3 “‘the prescription medication is medically necessary, up-to-date, and non-duplicative’ and ‘[Prescribing
 4 Doctors] are not violating state or federal law applicable to the provision of their services’ because they
 5 had accepted money in exchange for those prescriptions”’ state mail and wire fraud claims for purposes
 6 of RICO). This Court should do the same.

7 **1. HCSC’s Off-Label Promotion Allegations State a Cause of Action.**

8 HCSC states a claim under New Jersey RICO and its other causes of action relying on off-label
 9 promotion because it alleges that Mallinckrodt misrepresented to HCSC that it was complying with
 10 federal law, when in fact, Mallinckrodt had violated federal law by promoting Acthar for off-label
 11 indications. *See* ¶¶ 13, 44–55, 121–146, 259, 267. Mallinckrodt’s representations concerning its
 12 compliance with the law were false. HCSC alleges who made the misrepresentation (Mallinckrodt), to
 13 whom it was made (HCSC), what it was (that Mallinckrodt complied with federal law), when it was
 14 made (when Mallinckrodt made Acthar-related certifications to HCSC), and by what means it was made
 15 (through Mallinckrodt’s certifications to HCSC). Contrary to Mallinckrodt’s argument (MPA at 27-28),
 16 the thrust of HCSC’s claims is **not** that the off-label promotions themselves were misrepresentations.
 17 Rather, it is the false statements of compliance with the law by Mallinckrodt (and Prescribing Doctors)
 18 that were false. Mallinckrodt’s arguments concerning lack of specificity are thus misguided. *See Humana*,
 19 2020 U.S. Dist. LEXIS 101378, at *48 (“Here, Plaintiff has alleged that the doctors prescribed Acthar
 20 because of the bribes and the availability of the co-pay assistance funds, and the false certifications from
 21 Defendant and the doctors directly caused Plaintiff to pay for Acthar in an amount and for a price
 22 higher than it otherwise would have absent the alleged illegal conduct.”).⁶

23 _____
 24 ⁶ Mallinckrodt’s reliance on *Wash. Cty. Bd. of Educ. v. Mallinckrodt ARD, Inc.*, 2020 U.S. Dist. LEXIS
 25 1020, at *28 (D. Md. Jan. 3, 2020), is misplaced as HCSC’s claims do not rely on the specifics of the
 26 off-label marketing scheme and HCSC does not plead the Maryland consumer statute at issue there.
 27 Mallinckrodt’s reliance on *U.S. v. Caronia*, 703 F.3d 149, 165-69 (2d Cir. 2012), is similarly misplaced.
 28 There, the court construed the Federal Food, Drug, and Cosmetics Act as not criminalizing the simple
 promotion of a drug’s off-label use because such a construction would raise First Amendment concerns.
Id. at 160. The court did not immunize a defendant for falsely representing that it had complied with
 statutes and regulations when, in fact, it had not; this type of fraud is not protected speech. *See Olivia*

1 To the extent more particulars are required about the inner-workings of Mallinckrodt's off-label
 2 scheme, that information is within Mallinckrodt's control and knowledge and need not be alleged for
 3 HCSC's fraud-based claims to withstand demurrer. *See Comm. on Children's Television, Inc. v. Gen. Foods*
 4 *Corp.*, 35 Cal. 3d 197, 216–17 (1983) ("Less specificity is required when it appears from the nature of
 5 the allegations that the defendant must necessarily possess full information concerning the facts of the
 6 controversy"). Here, the allegations are "sufficient to enable the court to determine whether, on the
 7 facts pleaded, there is any foundation, prima facie at least, for the charge of fraud." *Id.* at 217 (quotations
 8 omitted). No more is needed.

9 Mallinckrodt argues HCSC fails to allege causation for its fraud-based claims. MPA at 28-29.
 10 Not so. HCSC alleges that it paid for Acthar prescriptions that it otherwise would not have because
 11 HCSC relied on Mallinckrodt's misrepresentation that Mallinckrodt had complied with the law. *See ¶¶*
 12 13, 44-55, 121-146, 259, 267, 275-78. No more is needed to sufficiently allege that Mallinckrodt's
 13 misrepresentations caused HCSC injury. *See Painters & Allied Trades Dist. Council 82 Health Care Fund v.*
 14 *Takeda Pharm. Co.*, 943 F.3d 1243, 1251 (9th Cir. 2019) ("Here, the alleged violation is that Defendants
 15 actively concealed Actos's risk of causing bladder cancer to sell more Actos to unsuspecting persons,
 16 thereby increasing Actos's revenue. And [payors'] alleged injury is that they purchased Actos
 17 prescriptions for which they would not have paid had they been warned about Actos's risk of bladder
 18 cancer. Because Plaintiffs were immediate victims of Defendants' alleged fraudulent scheme to conceal
 19 Actos's risk of bladder cancer, the alleged RICO violation ... has a direct relation to Plaintiffs' alleged

20
 21 *N. v. Nat'l Brod. Co.*, 74 Cal. App. 3d 383, 388 (1977) (misrepresentation is among the "narrowly limited
 22 classes of speech [which] may be prevented or punished by the state consistent with the principles of
 23 the First Amendment."). *Caronia* has limited application outside of the criminal context. *See Ariz. v.*
 24 *Medtronic Inc.*, 41 F. Supp. 3d 783, 795 (D. Ariz. 2014) ("*Caronia* was an appeal of a criminal case and the
 25 court considered whether the FDCA criminalized off-label promotion of prescription drugs. ... The
 26 court said that the misbranding provisions of the FDCA do not prohibit and criminalize 'the truthful
 off-label promotion of FDA-approved prescription drugs,' and then stated that its conclusion was
 'limited to FDA-approved drugs for which off-label use is not prohibited[.]' ... This case involves
 allegations of misrepresentation in off-label promotion of a Class III medical device. *Caronia* is not
 relevant to this claim, nor are the district court cases cited by Defendants that have relied on it.").

1 harm.”).

2 Similarly, Mallinckrodt’s contention that doctors’ “independent medical judgment” breaks a
 3 causal chain is inconsistent with the allegations of the complaint and has been rejected by the Ninth
 4 Circuit in *Painters* and numerous courts. *See, e.g., In re Neurontin Mktg. & Sales Practices Litig.*, 712 F.3d 21,
 5 39 (1st Cir. 2013) (rejecting argument that there were too many steps in causal chain between
 6 defendant’s off-label promotion and insurance company’s injuries); *In re Avandia Mktg.*, 804 F.3d 633,
 7 645–46 (3d Cir. 2015) (rejecting argument “that the presence of intermediaries, doctors and patients,
 8 destroys proximate causation” of insurance company’s injuries flowing from defendant’s fraudulent
 9 pharmaceutical marketing); *United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165, 2014 U.S. Dist.
 10 LEXIS 99815, at **30–32 (C.D. Cal. July 10, 2014) (“To suggest that [defendant’s] alleged expansive,
 11 multi-faceted efforts to create an off-label market for Thalomid and Revlimid did not cause physicians
 12 to prescribe Thalomid or Revlimid for non-reimbursable uses strains credulity.”).⁷ Exactly these same
 13 arguments were rejected in *Humana*. U.S. Dist. LEXIS 101378, at *47 (“here the doctors were allegedly
 14 bribed to prescribe Acthar and were participants in the RICO conspiracy. That causal link is far from
 15 attenuated.”).

16 Mallinckrodt’s reliance on *Sidney Hillman Health Center v. Abbott Labs.*, 873 F.3d 574, 577 (7th
 17 Cir. 2017) and *UFCW Local 1776 v. Eli Lilly & Co.*, 620 F.3d 121, 134 (2d Cir. 2010) is misplaced because
 18 in those cases misrepresentations were made *to the doctors*, who were **innocent** conduits of the alleged
 19 falsehoods. There were no allegations that payors *themselves* relied on the false representations, and this
 20 was a “crucial[]” factor negating proximate cause. *UFCW*, 620 F.3d at 134; *Sidney Hillman*, 873 F.3d at
 21 578 (distinguishing itself from case where “misrepresentations are made directly to Payors”). Here, by
 22 contrast, HCSC alleges that it was *itself* the victim of misrepresentations made directly by Mallinckrodt.

24 ⁷ HCSC construes these arguments to apply to its claims for unfair and deceptive practices, Count V of
 25 the Complaint, as well as other claims that require causation such as unjust enrichment (Count IX). *See*
 26 MPA at 26 n.9. With respect to Count IX, this appear to be the sole challenge and any further arguments
 27 concerning this Count on reply are waived. *See Magic Kitchen LLC v. Good Things Int’l, Ltd.*, 153
 28 Cal.App.4th 1144, 1161 (2007) (“Contentions are waived when a party fails to support them with
 reasoned argument and citations to authority . . . The waiver is not cured by argument and citations in
 [a] reply brief: It is elementary that points raised for the first time in a reply brief are not considered by
 the court.”).

Mallinckrodt argues that because HCSC “pre-reviewed” certain claims, HCSC’s fraud claims are too attenuated. MPA at 26, 28. However, no causal chain was broken by HCSC’s claim review process, as the process was tainted by Mallinckrodt’s conduct and whatever HCSC may have reviewed did not disclose the crucial aspects of the scheme. *See Neurontin*, 712 F.3d at 38–41 (discussing how off-label promotion influences third party payor’s coverage determinations and rejecting argument that there are too many steps in causal chain between defendant’s off-label promotion and insurance company’s injuries). The argument also ignores the allegation that HCSC relied on physicians’ representations that the prescription was medically necessary, which representations, as discussed above, were influenced by the off-label promotion scheme. *See* ¶ 271.

2. HCSC's Physician Kickback Allegations State a Cause of Action.

Mallinckrodt argues that HCSC's claims related to payments to physicians fail because (1) HCSC's bribery allegations are conclusory, and (2) facts concerning causation are lacking. MPA 24 to 27. Mallinckrodt's contentions contest the truth of the facts alleged, or ignore them altogether, and must be rejected.

HCSC alleges that payments Mallinckrodt made to physicians constitute undisclosed unlawful kickbacks supporting RICO and state law causes of action. *See* ¶ 14 (“Mallinckrodt funneled millions of dollars to thousands of doctors to encourage the use of Acthar as a first-line treatment and to promote the five-day dosing regimen. Mallinckrodt paid bribes thinly disguised as compensation for speaking engagements and sham clinical research studies, and even paid undisguised bribes such as gift cards to doctors’ staff.”); *see also* ¶¶ 149-161 (identifying specific instances), 220 (alleging these practices violate RICO). Mallinckrodt does not dispute that HCSC sufficiently alleges that these payments constituted unlawful kickbacks in violation of the Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); *see also* ¶¶ 38-43.⁸ Contrary to Mallinckrodt’s assertion (MPA at 26), HCSC sufficiently alleges that the unlawful physician kickbacks caused HCSC injury as Mallinckrodt and Prescribing Physicians made false statements about compliance with kickbacks and bribery laws. *See* ¶¶ 267, 271, 274, 278, 283 (“The

⁸ That sometimes HCSC labels the kickbacks as bribes is of no import.

1 compliance certifications were material to HCSC decision to reimburse claims for Acthar that
2 Mallinckrodt caused to be submitted.”).

3 Mallinckrodt’s arguments concerning bribery being conclusorily alleged are not well-taken, even
4 if the Court agrees with Mallinckrodt that federal pleading standards apply.⁹ Contesting the facts
5 supporting causation, Mallinckrodt posits that the payments are simply “industry standard” (MPA at
6 25), and supporting studies such as the 2018 JAMA Network study showing with regression analysis
7 that the percentage of doctors who receive financial assistance for prescribing Acthar is abnormally high
8 get it wrong. *Id.* at 25-26. These arguments cannot be resolved by demurrer. *Comm. On Children’s*
9 *Television*, 35 Cal. 3d at 213 (a demurrer does not “test the truth of the plaintiff’s allegations or the
10 accuracy with which he describes the defendant’s conduct”). In any event, the JAMA study supports
11 HCSC’s allegations that the payments from Mallinckrodt influenced doctor’s decision to prescribe
12 Acthar, and the extent to which that is true will be determined in discovery. *See* ¶ 158 (“JAMA Network
13 Open concluded that ‘[a]ggressive sales tactics and payments from [Mallinckrodt] may influence
14 prescribing behavior for [Acthar].’”).

15 Mallinckrodt’s causation arguments are misguided as they sweep aside the allegations that
16 physicians did not, in fact, exercise “independent medical judgment.” *See* ¶¶ 149, 150, 152, 154, 157;
17 *Blue Cross of Cal. Inc. v. Insys Therapeutics Inc.*, 390 F. Supp. 3d 996, 1008 (D. Ariz. 2019) (“The thrust of
18 [defendant’s] argument . . . is that, when prescribing Subsys, providers were exercising their independent
19 medical judgment, which breaks the causal chain between [defendant’s] actions and [plaintiff’s] alleged
20 injury. As pled, however, the complaint alleges that prescribers were not exercising independent medical
21 judgment. That is, prescribers were prescribing Subsys in exchange for kickbacks.”); *United States ex rel.*
22 *Westmoreland v. Amgen, Inc.*, 812 F. Supp. 2d 39, 53 (D. Mass. 2011) (“Kickbacks are designed to influence
23 providers’ independent medical judgment”); *State ex rel. Wilson v. Superior Court*, 227 Cal. App. 4th 579,

24
25
26 ⁹ Mallinckrodt’s characterization of HCSC’s allegations is inaccurate. *See* ¶ 159 (“Although speakers were
27 compensated on the high end of the industry standard, what qualified as a speaking engagement for
28 which the speaker was compensated was a very low bar. Only as few as three people- who need not be
physicians- were required to attend for a physician to be eligible for the full fee. Even spouses were
allowed to attend”). Considered in full context, HCSC is not admitting payments to physicians and their
families were “industry standard,” but is alleging the opposite.

606-07 (2014) (“Given a choice among two or more medically appropriate drugs, the reasons why a physician would prescribe one over another could include many possible factors, including not just the physician's independent medical judgment as to the particular prescription, but also, for example, patient requests and preferences, direct advertising, relative costs of alternative treatments and drugs, dictates of institutional formularies, availability of particular drugs, insurance company preferences, and—of course—the unlawful conduct [unlawful physician kickbacks] in which [defendant] had engaged to induce such prescriptions.”).

Finally, Mallinckrodt argues that its settlement with regulators does not support an inference of wrongdoing generally, or alternatively that only misconduct from 2009 to 2013 is alleged. MPA at 25.¹⁰ The DOJ settlement strongly supports HCSC’s claims that Mallinckrodt made illegal payments to prescribing physicians. *See, e.g., In re Nat’l Ass’n of Music Merchants, Musical Instruments & Equip. Antitrust Litig.*, 2011 WL 3702453, at *2 (S.D. Cal. Aug. 22, 2011)(denying motion to strike references to FTC complaint and consent decree from pleading and holding that FTC consent decree enhanced plausibility of anticompetitive conduct allegations). Whatever weight the Court may give the settlements, however, HCSC provides ample supporting facts demonstrating a marketing scheme that persisted over many years, including details about specific payments to certain physicians. ¶¶ 121-161. HCSC’s allegations that Mallinckrodt, at minimum, paid over \$27 million in improper payments “from 2013 to 2016” (¶ 156) is dispositive of Mallinckrodt’s contention that the wrongdoing is limited in time.

C. HCSC States a Cause of Action for Tortious Interference With Contracts

Mallinckrodt argues HCSC has not stated a claim for intentional interference because there has been no breach of contract by HCSC’s customers. MPA at 24. As the California Supreme Court has held, however, a claim can be stated by either “actual breach or disruption of the contractual relationship.” *Pacific Gas & Electric Co. v. Bear Stearns & Co.*, 50 Cal.3d 1118, 1126 (1990) (citations omitted). Here, HCSC explicitly alleges disruption of contractual benefits because Mallinckrodt

¹⁰ That the amount of Mallinckrodt’s payments to doctors may have been public in 2014 is not controlling. *See* MPA at 26. The true nature and purpose of the payments, i.e., that they were unlawful kickbacks, was not discovered until much later. *See* ¶¶ 177-180..

1 knowingly frustrated the operation of co-pay obligations that are designed to benefit all members by
 2 keeping costs low. ¶¶ 286, 288.

3 The Office of Inspector General (“OIG”) advisory bulletin quoted by Mallinckrodt (MPA at
 4 24) is not dispositive of HCSC’s tortious interference claim. That bulletin relates to *only* Medicare Part
 5 D beneficiaries, not other HCSC members. *See* Defs’ RJN, Ex. A (guidance entitled “Patient Assistance
 6 Programs for Medicare Part D Enrollees”); *cf.* ¶ 18 (“HCSC . . . provides . . . private commercial health
 7 insurance plan benefits that cover the medical expenses incurred by plan beneficiaries on an individual
 8 or group basis.”). Because the court in *Humana* exclusively relied on the OIG guidance in dismissing
 9 the tortious interference claims, reliance on that case is misplaced. *See* MPA at 24; *Humana*, 2020 U.S.
 10 Dist. LEXIS 101378, at ** 49–50.¹¹

11 **D. Mallinckrodt’s Insurance Fraud is Actionable**

12 In its request for judicial notice, Mallinckrodt argues that HCSC’s claims under the laws of
 13 California and other states that purportedly do not provide a private right of action should be dismissed,
 14 and that claims for states that provide such a private right are time-barred, or otherwise deficient. MPA
 15 at 17, n. 2. These arguments are not properly raised, as demonstrated in HCSC’s opposition to
 16 Mallinckrodt’s RJN. Mallinckrodt’s recitation of the law is inaccurate in some respects and legal claims
 17 should not be resolved through request for judicial notice. More specifically, Mallinckrodt is wrong that
 18 California, Kentucky, New Jersey, and Florida provide no private right of action in these circumstances.

19 Although many states do not have express rights of action for insurance fraud, such a right
 20 should be inferred here. A number of states have insurance fraud statutes in states that allow a
 21 government enforcer to pursue civil penalties for insurance fraud.¹² For these states that do not
 22

23
 24 ¹¹ Mallinckrodt’s reliance on *Blue Cross of California Inc. v. Insys Therapeutics Inc.*, 390 F.Supp.3d 996, 1009
 25 (D. Az. 2019), is unavailing. That claim does not apply California law, and plaintiff did not allege that
 defendant “induced or caused a breach of this provisions of the members’ contracts. . . . At most,
 [plaintiff] allege[d] that [defendant] interfered with a ‘**contractual incentive**.’” *Id.*

26 ¹² These statutes are: Ariz. Rev. Stat. §§ 20-463, et seq.; Ark. Code §§ 23-66-501, et seq.; Colo. Rev. Stat.
 27 § 10-1-128, et seq.; Iowa Code Ann. §§ 505.1, et seq.; Me. Rev. Stat. Ann. tit. 24-A, §§ 2186; Md. Code
 28 Ins. §§ 27-401, et seq.; Mo. Rev. Stat. §§ 375.99, et seq.; Mont. Code §§ 33-1-1202, et seq.; Neb. Rev.
 Stat. §§ 44-6604, et seq.; N.D. Cent. Code §§ 26.1-01, et seq.; N.M. Stat. §§ 59A-16C-1, et seq.; Okla.
 Stat. tit. 36, §§ 101, et seq.; and S.C. Code §§ 38-55-570, et seq.

1 expressly provide a private cause of action, this Court should recognize an implied private cause of
 2 action in the statute. Many states have examined statutes similar to the insurance fraud statutes here and
 3 concluded that a private right of action exists even when it is not express in the statutory scheme. *See,*
 4 *e.g. Allstate Ins. Co. v. Parfrey*, 830 P.2d 905 (Colo. 1992) (concluding private right of action existed for
 5 violation of statute requiring that automobile liability insurers provide uninsured/underinsured motorist
 6 coverage to their insureds); *Napoletano v. CIGNA Healthcare of Connecticut, Inc.*, 680 A.2d 127, 145 (Conn.
 7 1996) (determining private cause of action implied in Public Act governing managed care organizations),
 8 *overruled on other grounds by Batte-Holmgren v. Commissioner of Public Health*, 281 Conn. 277, 284-85 (2007). If
 9 the plaintiff is one for whose benefit the statute was enacted, there was expressly or implied legislative
 10 intent to create such a remedy, and it is consistent with the underlying purpose of the statute to imply
 11 such a remedy for the plaintiff, then a private remedy is implicit in the statute. *See Cort v. Ash*, 422 U.S.
 12 66 (1975).

13 An implied private right of action should likewise be recognized under the statutes at issue here.
 14 *See* fn. 12. All of the insurance fraud statutes are designed to benefit those paying increased costs due
 15 to insurance fraud, and so payors like HCSC would fall within this specific group of plaintiffs. The
 16 statutes here have not express prohibition on private litigants pursuing actions, which they would have
 17 done if they wanted to forbid private actions. Finally, the purposes of the insurance fraud statutes are
 18 to deter this type of conduct and recouping some of the overcharges that result from this fraud.
 19 Allowing a private cause of action under the insurance fraud statute would accomplish both of these
 20 goals.

21 **E. HCSC's Claims Are Timely.**

22 Mallinckrodt seeks dismissal based on the statute of limitations for HCSC's claims flowing from
 23 the CDF Co-Pay Scheme and its acquisition of Synacthen. MPA at 22–24, 33–34. Mallinckrodt relies
 24 on facts from purportedly judicially noticeable documents, which cannot be used on demurrer to resolve
 25 factual disputes about issues such as notice for purposes of the statute of limitations. *StorMedia, Inc. v.*
 26 *Superior Court*, 20 Cal.4th 449, 457, fn. 9 (1999) (“When judicial notice is taken of a document, however,
 27 the truthfulness and proper interpretation of the document are disputable.”). Although the wrongdoing
 28 alleged by HCSC stretches back over ten years, HCSC alleges it did not become aware of the scheme

1 now alleged until federal investigations, including the FTC’s investigation of antitrust claims and the
 2 DOJ’s claims concerning fraudulent sales practices, were disclosed. ¶¶ 180, 177 (“Mallinckrodt also
 3 failed to disclose to HCSC its arrangements with CDF that created specialized funds that were illegally
 4 to reimburse co-payments for Acthar”); *see also* Plaintiffs’ Request for Judicial Notice, Ex. 1-3 (certain
 5 facts supporting HCSC’s claims were made public in March and June 2019). None of the facts or
 6 documents Mallinckrodt seeks to judicially notice can defeat these allegations. Moreover, the doctrines
 7 of fraudulent concealment and ongoing violation make all of HCSC’s claims timely.

8 As an initial matter, HCSC is a putative class member in two separate class actions filed in April
 9 and October of 2017. *See City of Rockford v. Mallinckrodt ARD, Inc.*, No. 3:17-cv-50107 (N.D. Ill.) and
 10 *MSP Recovery Claims, Series LLC et al v. Mallinckrodt ARD Inc., et al.*, No. 2:17-cv-07928 (C.D. Cal.). With
 11 respect to its antitrust claims, HCSC is entitled to tolling as of the date those complaints were filed,
 12 because in those cases HCSC is a putative member of the classes and its antitrust claims share a common
 13 factual and legal basis with the class claims. *Am. Pipe & Constr. Co. v. Utah*, 414 U.S. 538 (1974). As none
 14 of HCSC’s claims are barred on the face of the Complaint or any materials Mallinckrodt seeks to include,
 15 these *Am. Pipe* issues need not be resolved at this time.

16 **1. Mallinckrodt’s Allegations Control and Defeat Mallinckrodt’s**
 17 **Arguments from Documents Outside the Pleadings.**

18 All of Mallinckrodt’s arguments fail because they rely on facts from judicially-noticed
 19 documents. These cannot be credited over HCSC’s allegations it discovered the wrongdoing when the
 20 results of government investigations became public. *Richtek USA, Inc. v. uPI Semiconductor Corp.*, 242 Cal.
 21 App. 4th 651, 660 (2015) (it is “improper” to consider on demurrer facts from a judicially noticed
 22 document that are “contrary to the allegations” in the complaint). For this reason alone, the demurrer
 23 must be overruled in its entirety.

24 Mallinckrodt argues that HCSC was on constructive notice of, and should have discovered, its
 25 claims “at least six years ago” because “the precise manner in which HCSC alleges the CDF funds
 26 violated the AKS has long been in the public record.” MPA at 22–23. The court in *Humana* rejected
 27 this precise argument. *Humana*, 2020 U.S. Dist. LEXIS 101378, at **33–37. Here, as in *Humana*, it “is
 28 not alleged . . . that Plaintiff was in any way notified whether co-pays were subsidized by assistance

1 funds. In fact, Plaintiff's allegations about its members indicate otherwise." *Id.* at *34; *see* ¶ 274
 2 ("Through its illegal scheme to pay patient co-pays through phony charitable funds at CDF,
 3 Mallinckrodt caused HCSC's members to unintentionally misrepresent that they had paid their
 4 contractual share of prescription drug coverage."). "The mere receipt or payment of claims, when there
 5 is no reason to think that Plaintiff knew those claims were fraudulent or excessive when it paid them,
 6 does not establish constructive knowledge of plaintiff's injury." *Humana*, 2020 U.S. Dist. LEXIS 101378,
 7 at *35 (quotations and brackets omitted).

8 As noted in *Humana*, there is nothing in HCSC's complaint "that indicates the allegedly illegal
 9 aspects of Defendant's co-pay assistance program were widely publicized, or that the information to be
 10 gleaned from the purported publicity could be imputed to Plaintiff." *Id.*, citing *Living Designs, Inc. v. E.I.*
 11 *Dupont de Nemours & Co.*, 431 F.3d 353, 365 (9th Cir. 2005) ("[T]he district court erred in determining
 12 that, as a matter of law, the attention received by [a sanction order against defendants] could be imputed
 13 to the Plaintiffs"). Further, HCSC alleges that the donation agreements fraudulently misrepresented that
 14 the funds were not limited to patients using Acthar. *See* ¶¶ 100, 108. Therefore, had HCSC "inquired
 15 into the funds, it would not have discovered that the funds were illegal." *See Humana*, 2020 U.S. Dist.
 16 LEXIS 101378, at *36.

17 Mallinckrodt contends that HCSC was put on constructive suspicion of its injuries by mere
 18 publication of two news articles and a guidance bulletin, the latter of which made no reference to Acthar.
 19 MPA 22-23. However, the concept of "constructive suspicion" was rejected in *Nelson v. Indevus Pharm.,*
 20 *Inc.*, 142 Cal.App.4th 1202, 1204–06 (2006); *id.* at 1206 ("The statute of limitations does not begin to
 21 run when some members of the public have a suspicion of wrongdoing, but only once the plaintiff has a
 22 suspicion of wrongdoing.") (quotations and brackets omitted); *see also Unruh-Haxton v. Regents of Univ. of*
 23 *Cal.*, 162 Cal.App.4th 343, 364 (2008) (rejecting idea "that public awareness of a problem through media
 24 coverage alone creates constructive suspicion for purposes of discovery."); *Gryczman v. 4550 Pico*
 25 *Partners, Ltd*, 107 Cal.App.4th 1, 6 (2003) ("we cannot say as a matter of law plaintiff had a duty to
 26 continually monitor public recordings"). Two articles, which themselves cast doubt on whether CDF
 27 was controlled by Mallinckrodt, cannot constitute notice under these circumstances. Ex. C at 21, 23
 28 (CDF received funds from Novartis, Genentech, Roche; "collaboration" was a "savvy move[]" that

1 increased stock price; and outside counsel represented “There is no steering that takes place
2 whatsoever.”); Ex. D at 27 (“Questcor and the charity have said they are victims of a campaign by short-
3 sellers”). Moreover, none of the materials cited by Mallinckrodt say anything of the off-label marketing,
4 or other aspects of the scheme to inflate demand.¹³

5 **2. Fraudulent Concealment Tolls HCSC’s Claims.**

6 HCSC’s claims are timely because Mallinckrodt fraudulently concealed its wrongdoing. “[T]he
7 fraudulent concealment by the defendant of a cause of action tolls the relevant statute of limitations,
8 which does not begin to run until the aggrieved party discovers the existence of the cause of action.”
9 *Cnty. Cause v. Boatwright*, 124 Cal. App. 3d 888, 899 (1981). HCSC alleges it could not have discovered
10 Mallinckrodt’s wrongdoing earlier because it repeatedly and falsely represented to HCSC it was
11 complying with federal law. ¶¶ 176; *see also* ¶¶ 114, 120, 177 (Mallinckrodt “falsely maintained that it
12 would develop and seek FDA approval of Synacthen”), 178.¹⁴ These allegations are sufficient to toll the
13 statute of limitations on HCSC’s claims.

14 **3. The “Continuing Violation” Doctrine Prevents Dismissal Because 15 Mallinckrodt Continues to Overcharge for Acthar.**

16 HCSC’s antitrust claims premised on the purchase of Synacthen continue to accrue because
17 HCSC alleges that it is suffering “continuing harm” in that it continues to pay for Acthar prescriptions.
18 *See* ¶ 181. “Antitrust law provides that, in the case of a ‘continuing violation,’ . . . each overt act that is
19 part of the violation and that injures the plaintiff, *e.g.*, each sale to the plaintiff, starts the statutory period

20 ¹³ Mallinckrodt’s authorities concerning when a plaintiff discovered she was injured have no application
21 because HCSC’s allegations control. *See Fox v. Ethicon Endo-Surgery, Inc.*, 35 Cal. 4th 797, 805 (2005)
22 (leave to amend granted to allege “why she did not have reason to discover earlier the factual basis”);
23 *Bernson v. Browning-Ferris Indus.*, 7 Cal. 4th 926, 938 (1994) (remanding case to determine “whether
24 plaintiff exercised reasonable diligence in attempting to discover defendants’ identity.”). Nor is
25 Mallinckrodt’s position supported by *Brandon G. v. Gray*, 111 Cal.App.4th 29 (2003), where the plaintiff
26 parents’ claims accrued from the date when they discovered, by examining the county’s files, that the
27 county had misrepresented the absence of complaints against the daycare facility. *Id.* at 34–36. Finally,
28 *McKelvey v. Boeing North American, Inc.*, 74 Cal.App.4th 151 (1999), cannot supply the rule here as it has
been abrogated by statute. *See Lopez v. Sony Electronics, Inc.*, 5 Cal.5th 627, 633 n.3 (2018) (“Legislature
also declared an intent to disapprove [McKelvey] to the extent that case put the burden on plaintiffs to
show they were unaware of published reports suggesting a defendant’s wrongdoing.”).

¹⁴ The FTC action concerning antitrust violations was publicized on January 18, 2017 (¶ 175). The
Department of Justice announced its action filed a detailed complaint in intervention on June 4, 2019
and made a press release the next day. *See* Pl.’s RJN Exs. 1, 3. Additionally, a separate *qui tam* complaint
with different allegations of off-label promotion was unsealed on March 8, 2019. *Id.*, Ex. 2. The DOJ
announced a settlement of these matters in September 2019. ¶ 161.

1 running again, regardless of the plaintiff's knowledge of the alleged illegality at much earlier times.” *Klebr*
 2 *v. A.O. Smith Corp.*, 521 U.S. 179, 189 (1997) (quotations omitted); *In re Pre-Filled Propane Tank Antitrust*
 3 *Litig.*, 860 F.3d 1059, 1065-66 (8th Cir. 2017) (“Every other circuit to consider this issue applies *Klebr*,
 4 holding that each sale in a price-fixing conspiracy is an overt act that restarts the statute of limitations”).
 5 The idea that “continued overcharges constitute a continuing violation” applies with equal force in drug
 6 monopoly cases. *In re Glumetza Antitrust Litig.*, 2020 U.S. Dist. LEXIS 39649, at **24–27 (N.D. Cal. Mar.
 7 5, 2020) (applying doctrine in action challenging reverse payment settlement and collecting cases); *see*
 8 *also In re Buspirone Patent & Antitrust Litig.*, 185 F.Supp.2d 363, 378 (S.D.N.Y. 2002) (“[I]f a party
 9 commits an initial unlawful act that allows it to maintain market control and overcharge purchaser for
 10 a period longer than four years, purchasers maintain a right of action for any overcharges paid within
 11 four years prior to their filings.”).

12 Mallinckrodt contends that the continuing violation doctrine does not apply “because once an
 13 acquisition is completed ‘no overt acts can be undertaken to further that plan.’” MPA at 33–34 (quoting
 14 *Midwestern Mach. Co., Inc. v. Northwest Airlines, Inc.*, 392 F.3d 265, 271 (8th Cir. 2004)). However,
 15 *Midwestern* is inapposite because it concerned a merger in violation of the Clayton Act, which has no
 16 continuing violation doctrine. *Id.* at 271 (“A continuing violation theory based on overt acts that further
 17 the objectives of an antitrust conspiracy in violation of § 1 of the Sherman Act or that are designed to
 18 promote a monopoly in violation of § 2 of that act cannot apply to mergers under § 7 of the Clayton
 19 Act.”).¹⁵

20 Here, HCSC alleges that Mallinckrodt’s acquisition of Synacthen and its subsequent shelving
 21 was in furtherance of its continuing monopoly in the ACTH market that included lying about the
 22 intentions of the transaction itself. ¶ 177; *cf. In re Evanston Northwestern Healthcare*, 2008 U.S. Dist. LEXIS
 23 42437, at *14 (N.D. Ill. May 29, 2008) (“Although it may be likely that plaintiffs knew or should have
 24 known of their potential injury at the time the merger was consummated, neither the legal precedents
 25 cited by ENH nor the allegations pleaded in plaintiffs’ complaint definitively require such a conclusion);
 26

27 ¹⁵ Mallinckrodt’s reliance on *Midwestern* to defeat fraudulent concealment is misplaced. *See* MPA at 34,
 28 relying on *Midwestern*, 392 F.3d at 272. *Midwestern* did not concern a claim of fraudulent concealment,
 nor did it concern a “catch and kill” scheme contrary to false claims to develop the drug. ¶ 177.

1 *see also Nexium*, 968 F.Supp.2d at 399–400 (rejecting similar argument based on *Midwestern*, explaining
 2 that “[a]lthough the business of a monopolist’s rival may be injured at the time the anticompetitive
 3 conduct occurs, a purchaser, by contrast, is not harmed until the monopolist actually exercises its illicit
 4 power to extract an excessive price.”).¹⁶

5 **F. Defendants’ Motion to Strike Is Improper.**

6 Along with their demurrer, Mallinckrodt challenges the sufficiency of HCSC’s allegations by a
 7 motion to strike, but a motion to strike “is not the proper method of attacking a pleading which is
 8 merely insufficient to state a cause of action, or defense, or which is defective in form.” *Allerton v. King*,
 9 96 Cal. App. 230, 233 (1929). Under Cal. Civ. Proc. Code 436(a) any “matter that is essential to a cause
 10 of action should not be struck and it is error to do so.” *Quiroz v. Seventh Ave. Ctr.*, 140 Cal. App. 4th
 11 1256, 1281 (2006). An argument that a complaint did not state facts sufficient to constitute a cause of
 12 action is ground for demurrer and is not, therefore, a proper ground for a motion to strike. *Ferraro v.*
 13 *Camarlinghi*, 161 Cal. App. 4th 509 (2008). Thus, allegations of wrongdoing such as would demonstrate
 14 knowledge, scienter, or a consistent behavioral practice remain relevant and should not be stricken,
 15 even if some of the alleged conduct occurred outside the limitations period. *Alch v. Superior Court*, 122
 16 Cal. App. 4th 339, 374 n.30 (2004) (“consideration of the entire scope of a hostile work environment
 17 claim, including behavior alleged outside the statutory time period, is permissible for the purposes of
 18 assessing liability, so long as any act contributing to that hostile environment takes place within the
 19 statutory time period.”) (quoting *AMTRAK v. Morgan*, 536 U.S. 101, 113 (2002)). Mallinckrodt’s use of
 20 a motion to strike is improper in three ways.

21 First, Mallinckrodt requests the court strike a multitude of factual allegations in the complaint
 22 that support otherwise valid causes of action, including: ¶¶ 11, 76-85 (Mallinckrodt has a vertically
 23 integrated distribution system); ¶¶ 12, 89-120, 273-75, 281, 323 (Mallinckrodt’s co-pay funds were
 24 fraudulent); ¶¶ 14, 149-61, 181, 257, 272-273 (Mallinckrodt funneled kickbacks to prescribing doctors);

25
 26 ¹⁶ *Z Techs Corp. v. Lubrizol Corp.*, 753 F.3d 594 (6th Cir. 2014), does not help Mallinckrodt either. There,
 27 the court recognized that the continuing violations doctrine applies to claims, where, as here, “a party
 28 unilaterally monopolized a market or undertook action, in addition to price increases, to monopolize a
 market.” *Id.* at 598; *id.* at 599 (“this court has applied the continuing violations doctrine . . . to unilateral
 monopolization claims when a party already possesses a monopoly and takes action to preserve the
 monopoly[.]”)

¶¶ 13, 121-48 (Mallinckrodt promoted Acthar off-label); ¶¶ 15, 162-76, 200, 203, 244-47, 249-53 (Mallinckrodt acquired and killed Synacthen). This is improper. Mallinckrodt fails to show how any of the individual paragraphs are irrelevant, false or improper; if the Court overrules Mallinckrodt's demurrer *a fortiori* they cannot be any of these things. A motion to strike is not a "line item veto."¹⁷

Second, Mallinckrodt moves to strike allegations regarding its settlement with the DOJ to resolve claims the company paid illegal kickbacks to physicians (¶ 161) and allegations regarding Mallinckrodt's settlement with the FTC of charges that it violated antitrust laws in its acquisition of an Acthar competitor (¶ 175). The FTC and DOJ settlements are relevant to HCSC's antitrust claims. *See, e.g., In re Nat'l Ass'n of Music Merchants, Musical Instruments & Equip. Antitrust Litig.*, 2011 WL 3702453, at *2 (S.D. Cal. Aug. 22, 2011)(denying motion to strike references to FTC complaint and consent decree). At minimum, facts developed in the FTC and DOJ matters will frame, in part, the scope of the factual and legal issues to be resolved here, and the actions taken help inform statute of limitations issues.

Third, Mallinckrodt seeks to have the court strike HCSC's state law claims for relief based on supposed legal deficiencies (¶¶ 245, 253, 257,¹⁸ and 280). Just as with the factual allegations above, the proper mechanism for challenging the legal sufficiency of these allegations is through a demurrer, not a motion to strike. And these paragraphs are necessary to describe the legal grounds under which HCSC is entitled to relief. Mallinckrodt's motion is without merit and should be denied.

VII. CONCLUSION

For the reasons set forth above, Mallinckrodt's demurrer should be overruled and the motion to strike should be denied. Should the Court be inclined to dismiss any aspect of HCSC's claims, HCSC respectfully requests leave to amend.

Dated: June 23, 2020

Respectfully submitted,

**SCHNEIDER WALLACE COTTRELL
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¹⁷ Mallinckrodt's own authorities demonstrate that "use of the motion to strike should be cautious and sparing" and that motions to strike do not create "a procedural 'line item veto' for the civil defendant." *PH II, Inc. v. Superior Court*, 33 Cal. App. 4th 1680, 1683 (1995). Mallinckrodt's motion to strike here is neither cautious nor sparing, and instead is precisely the sort of line-item veto that *PH II* cautioned against.

¹⁸ Mallinckrodt incorrectly cites paragraph 245 in its motion to strike.

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EXHIBIT 38

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SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**PLAINTIFF HEALTH CARE SERVICE
CORP.'S OPPOSITION TO REQUEST
FOR JUDICIAL NOTICE IN SUPPORT
OF THE DEFENDANT
MALLINCKRODT ENTITIES'
DEMURRER AND MOTION TO
STRIKE**

Judge: Hon. Stephen Kaus
Location: Dept. 19
Hearing: August 5, 2020; 3:00 p.m.
Complaint Filed: February 27, 2020

Trial Date: Not Set

1 I. INTRODUCTION

2 Defendants Mallinckrodt ARD LLC and Mallinckrodt plc (together, “Mallinckrodt”) request
 3 that this Court take judicial notice of a number of documents issued created by federal regulators. As
 4 explained below, Plaintiff Health Care Service Corporation (“HCSC”) objects to Mallinckrodt’s
 5 repeated attempts to judicially notice the truth of contents in documents, even if the documents are
 6 otherwise judicially noticeable. The Court should reject Mallinckrodt’s use of Exhibits A through D,
 7 H, and I because they are used to contest the facts pled by HCSC. The Court should deny judicial
 8 notice of Exhibits K through O because each exhibit is problematic in at least one way, and each is
 9 unnecessary to the resolution of Mallinckrodt’s motion to strike. The Court should deny judicial
 10 notice of Exhibit E because, although potentially judicially noticeable, it is nowhere cited and
 11 therefore irrelevant.

13 II. LEGAL STANDRD FOR JUDICIAL NOTICE

14 Matters are “subject to judicial notice only if the matter is reasonably beyond dispute.” *Tenet*
 15 *Healthsystem Desert, Inc. v. Blue Cross of California*, 245 Cal. App. 4th 821, 835 (2016). A demurrer may
 16 not be turned into a contested evidentiary hearing through the guise of having the court take judicial
 17 notice of documents whose truthfulness or proper interpretation are disputable. *Fremont Indem. Co. v.*
 18 *Fremont Gen. Corp.*, 148 Cal. App. 4th 97, 114 (2007). While the existence of a document may be
 19 judicially noticeable, the truth of statements contained in the document and their proper
 20 interpretation are not subject to judicial notice. *Tenet Healthsystem Desert, Inc.*, 245 Cal. App. 4th 821 at
 21 836; *see also Aquila, Inc.*, 148 Cal. App. 4th at 569 (“[T]he taking of judicial notice of the official acts of
 22 a governmental entity does not in and of itself require acceptance of the truth of factual matters which
 23 might be deduced therefrom”).

26 III. ARGUMENT

27 A. Mallinckrodt Improperly Seeks to Judicially Notice Disputed Facts.

28 California courts draw a distinction between judicial notice of the existence of a document,

1 and judicial notice of the truth of the contents of a document. “Strictly speaking, a court takes judicial
 2 notice of facts, not documents.” *Scott v. JPMorgan Chase Bank, N.A.*, 214 Cal. App. 4th 743, 755 (2013).
 3 Thus while courts are permitted to take judicial notice of the “existence” of documents in ruling on a
 4 demurrer, as the California Supreme Court explained in *StorMedia Inc. v. Superior Court*, 20 Cal. 4th 449,
 5 457 n.9 (1999), “[w]hen judicial notice is taken of a document... the truthfulness and proper
 6 interpretation of the document are disputable.” While “a court may take judicial notice of a recorded
 7 deed, or similar document,” the Court may not “take judicial notice of factual matters stated therein.”
 8 *Poseidon Dev., Inc. v. Woodland Lane Estates, LLC*, 152 Cal. App. 4th 1106, 1117 (2007).

9 Mallinckrodt disregards these well-established principles in seeking to cherry-pick statements
 10 from documents outside the pleadings in support of its demurrer and motion to strike.

11 1. **Mallinckrodt Improperly Relies on Facts in Exhibits A through D to**
 12 **Make Arguments Regarding the Statute of Limitations.**

13 Mallinckrodt improperly relies on the truth of matters contained in Exhibits A through D to
 14 argue that HCSC was on “constructive notice” of the facts and how they relate to HCSC’s claims.
 15 MPA at 23-24. It is well established that a court may not use media sources to create “constructive
 16 suspicion” of the existence of facts to trigger the statute of limitations, as this requires the Court to
 17 accept the contents of the materials as true. *Unruh-Haxton v. Regents of Univ. of Cal.*, 162 Cal. App. 4th
 18 343, 365 (2008) (“the court interpreted the widespread media coverage to conclusively refute the
 19 patients’ allegations they either (1) did not see or read the media coverage, or (2) saw the publicity, but
 20 failed to discover any wrongdoing. [J]udicial notice was improperly taken in both instances.”). HCSC
 21 was not required to accept the reporting as true, particularly where Mallinckrodt and CDF issued
 22 categorical and qualified denials. *See* RJN Ex. C at 23 (outside counsel represented “There is no
 23 steering that takes place whatsoever.”); Ex. D at 27 (“Questcor and the charity have said they are
 24 victims of a campaign by short-sellers”). In any event, Mallinckrodt improperly uses Exhibits A
 25 through D to create constructive notice and its request should be denied.¹

26 _____
 27 ¹ *Hurwitz v. Hoefflin*, 84 Cal. App. 4th 1232, 1235 n.1 (2000), cited by Mallinckrodt, recognizes that
 28 courts “cannot and do not take judicial notice of the truth of the matters contained therein.” *See also*
Ragland v. U.S. Bank Nat’l Ass’n, 209 Cal. App. 4th 182, 193, 147 (2012) (“While we may take judicial

1 Mallinckrodt's request with respect to two news articles from *Barron's* and *The New York Times*
 2 is an improper attempt to introduce evidence of when HCSC was on notice of certain allegations. *See*
 3 RJN Ex. C and D; *see also Voris v. Lampert*, 7 Cal. 5th 1141, 1147, (2019) (declining to take judicial
 4 notice of newspaper articles that were "not proper authorities to establish the truth of the matters
 5 asserted therein."); *People ex rel. Lockyer v. Shamrock Foods Co.*, 24 Cal. 4th 415, (2000) (refusing to take
 6 judicial notice of articles not relevant to state statutory issue).

7 Similarly, Mallinckrodt relies on guidance from the Department of Health and Human
 8 Services Office of Inspector General ("OIG") concerning co-payments for Medicare Part D enrollees
 9 in 2005 (Ex. A) and May 2014 (Ex. B) arguing they provide "constructive notice" to HCSC. MPA at
 10 22. This is another improper use of judicial notice. Neither document can be used to establish a date
 11 of discovery that is different from that which is alleged by HCSC. HCSC alleges it discovered the
 12 wrongdoing after federal investigations were made public. Those allegations are entitled to the
 13 presumption of truth. *Richtek USA, Inc. v. uPI Semiconductor Corp.*, 242 Cal. App. 4th 651, 660 (2015) (it
 14 is "improper" to consider on demurrer facts from a judicially noticed document that are "contrary to
 15 the allegations" in the complaint).

16 Exhibits A and B cannot provide any type of constructive notice because they disclose no
 17 wrongdoing. Neither Exhibit A nor B mentions Acthar at all, and in no sense would they put a
 18 reasonable person on notice of any wrongdoing. Nor does Exhibit A establish that HCSC reviewed
 19 this document in 2005—prior to when the wrongdoing alleged here began—or at any other time.
 20 With respect to Exhibit B, it too has no indicia of HCSC having reviewed it.

21 2. **Mallinckrodt Makes Improper Use of Exhibits I & H to Dispute the** 22 **Truth of Other Facts HCSC Alleges.**

23 Mallinckrodt seeks judicial notice of facts contained within a DOJ press release (Ex. H), which
 24

25 _____
 26 notice of the existence of the audit report, Web sites, and blogs, we may not accept their contents as
 27 true").
 28

1 Mallinckrodt seeks to use to establish the fact that the DOJ allegations “were limited to the conduct
2 of ‘twelve Questcor sales representatives’ ‘from 2009 and 2013.’” RJN at 4. Mallinckrodt uses Ex. H
3 to invent a fact—that its sales representative misconduct ended in 2013—that is not found anywhere
4 in press release. MPA at 25 (“The settlement would not support HCSC’s claim for damages between
5 2014 and the present, and it should be stricken from the complaint as irrelevant matter....”).
6 Mallinckrodt improperly uses this document to establish the truth of its contention that there was no
7 actionable misconduct concerning sales representatives from 2014 to the present. This is contradicted
8 by HCSC’s specific allegations that identify similar kickbacks and improper payments to doctors into
9 2016. ¶¶ 156-158. The DOJ’s Complaint in intervention contradicts the fact Mallinckrodt improperly
10 seeks to notice. *See* Pl.’s’ Request for Judicial Notice, Ex. 2; Complaint, *United States of America ex rel.*
11 *Strunck*, No. 12-cv-0175 (E.D. Pa. June 4, 2019) at Exhibits 1 to 4 (alleging and documenting false
12 claims through 2014).

13 Mallinckrodt similar makes improper use of judicial notice in seeking notice Exhibit I, an
14 article published in the JAMA Open Network in 2018 that Mallinkrodt contends makes certain of
15 HCSC’s allegations “implausible.” *See* MPA at 25-26. The JAMA study supports HCSC’s allegations
16 that the payments from Mallinckrodt influenced doctor’s decision to prescribe Acthar by comparing
17 the correlation between payments to prescribing doctors and Acthar prescriptions written, finding a
18 statistically significant correlation. *See* ¶ 158 (“JAMA Network Open concluded that ‘[a]ggressive sales
19 tactics and payments from [Mallinckrodt] may influence prescribing behavior for [Acthar].’”). As a
20 threshold matter, scientific articles that have bearing on disputed issues cannot be judicially noticed.
21 *People v. Ireland*, 33 Cal. App. 4th 680, 685 (1995) (“As to the scientific literature, we take judicial notice
22 only to the existence of the writings; the truth of the scientific claims written about cannot be
23 judicially noticed, but must be proved, since some of those claims are currently the subject of
24 controversy.”)

25 Mallinckrodt contends that because the JAMA article says its “conceivable” that something
26 else other than bribes was causing the high incidence of prescription, HCSC’s allegation is
27 implausible. *See* RJN Ex. I at 84 (“[T]he temporal sequence between payments and prescriptions
28 cannot be definitely established.”). Once again, Mallinckrodt attempts to extrapolate from documents

1 the truth of a fact that is found nowhere in the document itself. The JAMA article expressly does **not**
 2 say that other behavior caused higher incidence of Acthar, it simply states that it studied the
 3 remarkable correlation and not the underlying causes. In any event, HCSC's other allegations strongly
 4 support causation. ¶¶ 153-154, 159 (alleging irregularities in Mallinckrodt's paid speaker programs and
 5 identifying specific abnormally large payments).

6 B. Mallinckrodt's Request to Judicially Notice Other State Laws and Cases Interpreting
 7 the Same Exceeds the Allowed Scope of Judicial Notice.

8 Mallinckrodt seeks judicial notice of five tables purporting to be compilations of out of state
 9 authorities relating to HCSC's state law claims. *See* RJN Exhibits K-O. These tables, however, are not
 10 complete quotations of the relevant statutes and only include cherry-picked sections, along with
 11 citations to caselaw that Mallinckrodt believes is favorable to the defense position. General
 12 suppositions about the legal developments cannot be judicially noticed. *See Barker v. Garza*, 218 Cal.
 13 App. 4th 1449, 1452, n 1 (2013) (declining to take judicial notice of article about model Drug Dealer
 14 Liability Act and portions of law review article interpreting same because information contained in
 15 those sources was reasonably subject to dispute and plaintiff did not provide sufficient information to
 16 determine if judicial notice is proper). HCSC objects to all of Exhibits K through O because they
 17 resemble self-published law review articles, which are not an enumerated part of the Evidence Code.
 18 *See Cty. of Orange v. Smith*, 132 Cal. App. 4th 1434, 1450 (2005) ("Evidence Code section 452
 19 enumerates the matters of which a court may take judicial notice. Law review articles are not listed in
 20 either of those statutory provisions.").

21 Mallinckrodt's presentation of the laws in the table are argumentative, and not a complete and
 22 accurate picture of the relevant statutory language.

23 **Exhibit K:** HCSC objects to the legal conclusions drawn in the Exhibit K, which purport to
 24 recite statutory enforcement mechanisms, as this is beyond the scope of appropriate judicial notice.
 25 Mallinckrodt's request is filled with improper contentions and arguments.² Mallinckrodt's contentions

26
 27 ² RJN Ex. K at 127, 129, 130 ("HCSC fails to allege actual injury from the alleged violation."); *id.* at
 28 129 (arguing HCSC's claims under New Jersey Insurance Fraud Prevention lack specificity); *id.* at 130
 (arguing HCSC's claims fail Pennsylvania pleading standard); *id.* (arguing claims under Tennessee

1 concerning application of states' laws is beyond the "decisional ... law" of a state that may be judicial
2 noticed under Evidence Code Section 452(a).

3 Mallinckrodt's recitation of these laws is also inaccurate. Mallinckrodt argues that Kentucky's
4 law requires a conviction for there to be a private right of action for insurance fraud claim (Ex. K at
5 127), but Kentucky repealed this provision in 2018. *See* Declaration of Matthew S. Weiler, Ex. 4 (2018
6 Kentucky Laws Ch. 178 (HB 323) (removing requirement of a "criminal adjudication of guilt" for a
7 private party to state a claim for damages)).

8 California permits insurers to bring *qui tam* actions for private insurance fraud. *See People ex rel.*
9 *Allstate Ins. Co. v. Sub*, 37 Cal.App.5th 253, 255 (2019); Cal. Ins. Code § 1871.7; Cal. Penal Code § 550.
10 Moreover, an insurance fraud claim does not require an affirmative misstatement of fact, only one
11 that is "characterized by deceit." *People ex rel. Allstate Ins. Co*, 37 Cal.App.5th 253 at 260. California's
12 Unfair Competition Law ("UCL") also allows for a private action violation predicated on violation of
13 the Insurance Code, and an implied private right of action where an express right does not exist. *See*
14 *Hangerter v. Paul Revere Life Ins. Co.*, 236 F. Supp. 2d 1069, 1107 (N.D. Cal. 2002) (allowing UCL claim
15 based on violation of California's insurance code); *Stevens v. Superior Court*, 75 Cal. App. 4th 594, 606,
16 (1999) (allowing violation of insurance code licensing requirements as basis for UCL claim because
17 UCL "allows nearly any law or regulation to serve as its basis unless the predicate statute explicitly
18 bars a private right of action.").

19 Contrary to Mallinckrodt's contention (Ex. K at 126), Florida permits a private insurer to
20 pursue a civil insurance fraud claim. *Molina v. Provident Life and Accident Ins. Co.*, 18-24413-CV, 2019
21 WL 3429889, at *3 (S.D. Fla. May 31, 2019), *report and recommendation adopted*, 18-24413-CIV, 2019 WL
22 7937935 (S.D. Fla. June 27, 2019). While Florida's statutes have incorporated criminal liability into the
23 statute, the requirement of a criminal conviction before pursuing a civil penalty has been thrown into
24 question. *See Nationwide Mut. Co. v. Ft. Myers Total Rehab Ctr., Inc.*, 657 F. Supp. 2d 1279, 1287 (M.D.
25 Fla. 2009) ("Nothing in this statute provides that a cause of action exists only if there is a conviction,
26 or that other causes of action are pre-empted."). Thus, the Court should allow HCSC's insurance
27

28 _____
Insurance Fraud Act are time-barred).

1 fraud claim under Florida law to proceed.

2 Similarly, Mallinckrodt argues that “HCSC fails to allege that it complied with the procedures
3 provided in the New Jersey Insurance Fraud Prevention Act.” Ex. K at 129. But the New Jersey IPFA
4 only requires that “pleadings” and “briefs” be sent to the New Jersey Attorney General “at the time of
5 filing.” N.J. Stat. § 17:33A-7(c). This procedural provision is not an element of a New Jersey insurance
6 fraud claim and is no basis for dismissal of HCSC’s claim. *Cf. In re Generic Pharm. Pricing Antitrust Litig.*,
7 368 F. Supp. 3d 814, 835 (E.D. Pa. 2019) (declining to dismiss claims under statutes with more
8 stringent pre-suit notice requirements because “they do not alter the substantive elements of
9 Plaintiffs’ claims and are not a pleading requirement for the Complaints”).

10 **Exhibit L:** HCSC objects to the entire exhibit, purportedly showing what states adopt the rule
11 of reason for certain vertical restraints, because it is irrelevant. Mallinckrodt supplies the laws to
12 support their contention that the exclusive distribution allegations should be viewed in isolation and
13 examined under the rule of reason. MPA at 18. Mallinckrodt’s characterization of states purportedly
14 “Adopting Rule of Reason for Nonprice Vertical Restraints” should be rejected as it mischaracterizes
15 HCSC’s allegations, which allege a price-fixing and monopolization scheme. As HCSC does not
16 simply allege vertical restraints, the Exhibit L supplies the wrong legal paradigm for HCSC’s claims.

17 The Court need not, at this juncture, determine whether HCSC’s claims are subject to the *per*
18 *se rule* of illegality or the rule of reason: “While courts generally assess exclusive dealing arrangements
19 under the rule of reason analysis, it is less clear that the rule of reason analysis applies here where
20 plaintiffs have alleged that the conspiracy included both the exclusive dealing arrangement and the
21 Synacthen Acquisition, which plaintiff argues deserves a ‘per se’ analysis. However, the court agrees
22 with plaintiffs that the court need not make this determination at this time.” *City of Rockford v.*
23 *Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730, 754 (N.D. Ill. 2019); *In re: EpiPen (Epinephrine Injection,*
24 *USP) Mktg., Sales Practices & Antitrust Litig.*, 336 F. Supp. 3d 1256, 2018 WL 3973153, at *19 n.8 (D.
25 Kan. 2018) (“In ruling [on a motion to dismiss], the court just needs to determine whether the class
26 plaintiffs have alleged a plausible conspiracy under the antitrust laws.”); *CSR Ltd. v. Fed. Ins. Co.*, 40 F.
27 Supp. 2d 559, 564 (D.N.J. 1998) (“At this early [motion to dismiss] stage of the proceeding, the court
28 does not find it necessary to determine which mode of analysis [per se or rule of reason] it will

ultimately employ in evaluating the defendants' activities."); *In re High-Tech Employees' Antitrust Litig.*, 856 F. Supp. 2d 1103, 1122 (N.D. Cal. 2012) ("Defendants' argument relies on the false assumption that the Court should apply a rule of reason analysis, but as the parties agree ... the Court need not decide now whether per se or rule of reason analysis applies. Indeed, that decision is more appropriate on a motion for summary judgment.").

Exhibits M & O: HCSC objects to Mallinckrodt's chart reciting state law unfair practices statutes of limitations and "other defenses" (Exhibit M), and statute of limitations for antitrust claims (Exhibit O), because none of the issues Mallinckrodt raises concerning the application of the statute of limitations can be resolved on the record before the Court on demurrer.

With respect to Exhibit M, as with Exhibit K, Mallinckrodt makes a number of legal arguments against the application of certain states' laws that is inappropriate for a request for judicial notice. *See* RJN Ex. M at 141 (Maine law claim barred based on contention "allegedly unlawful conduct discontinued over five years before HCSC filed its Complaint"); *id.* (Michigan law claim barred based on exemption defense); *id.* (Minnesota law claim barred as only injunctive relief and attorneys' fees may be recovered); *id.* at 142 (raising as a defense privity under North Dakota law); *id.* (arguing HCSC's purchases were outside scope of consumer statute); *id.* at 143 (same with respect to Vermont law). The Court should deny judicial notice of these arguments and disregard them in resolving Mallinckrodt's demurrer and motion to strike.

With respect to Exhibit O, judicial notice of the statute of limitations period needs to be considered in connection with rules concerning accrual, as well as HCSC's allegations of continuing violation and fraudulent concealment. It would be a waste of judicial resources to judicially notice these materials in a vacuum, when none of these laws require dismissal here.

Exhibit N: Exhibit N, purporting to summarize various state laws concerning antitrust injury, is irrelevant. The Court need not judicially notice dozens of state laws when resolving the demurrer because under *any* state's law HCSC pleads the common sense elements of antitrust injury, namely that "but for Mallinckrodt's monopolistic conduct, including its acquisition of Synacthen, HCSC would have benefitted from increased competition in the market for ACTH drugs and would have either paid lower prices for Acthar or steered its members to lower priced Synacthen." ¶ 214.

1 Finally, HCSC objects to Exhibits K through O to the extent it seeks an end-run around the
 2 parties' agreed-upon 25 pages limit by attempting to litigate the state law claims through judicial
 3 notice, instead of briefing the issues through development of evidence and legal analysis.

4 C. Mallinckrodt's Request for "Mandatory" Judicial Notice Must Be Denied In Part.

5 Mallinckrodt claims that discretionary judicial notice can automatically become mandatory and
 6 seeks mandatory notice of facts contained in Exhibits E through H, and K through O. RJN at 3-5.
 7 Judicial notice can be mandatory or discretionary. Certain matters, such as the laws of the state of
 8 California or the Federal government, must be judicially noticed. *See* Cal. Evid. Code § 451 (a). Other
 9 records may be judicially noticed if an adverse party has notice of the request and the party requesting
 10 notice has furnished the court with sufficient information to enable the court to take notice. *See Id.* §§
 11 452 and 453. Mallinckrodt's request for mandatory notice is improper in two ways.

13 First, the Court at all times maintains the discretionary power to decline to take judicial notice
 14 Cal. Evidence Code §455(a) (information on the matter and the tenor of the matter to be noticed is
 15 required). As noted above, much of the law that Mallinckrodt seeks to judicially notice is improper
 16 argument or characterization, and is not necessary to the resolution of the demurrer because factual
 17 matters, such as the relevant dates to resolve statute of limitations, are disputed. More specifically,
 18 although included in its RJN, Mallinckrodt does not cite to Exhibit E anywhere in its demurrer or
 19 supporting memorandum of law, and so the Court should not take judicial notice because the
 20 document is not relevant. *Aquila, Inc. v. Superior Court*, 148 Cal. App. 4th 556, 569 (2007) (only
 21 "relevant material may be noticed.").

23 Second, Mallinckrodt must provide the Court with "sufficient information." Cal. Evidence
 24 Code § 453(b). If information the requesting party supplied to the court is not sufficient, the trial
 25 court is entitled to refuse to take judicial notice of matter requested. *People v. Moore*, 59 Cal. App. 4th
 26 168, 177 (1997). As shown above, judicial notice of certain principles of antitrust laws (Ex. L), and the
 27 statute of limitations (Exs. N & O) require the context of consideration of other points and
 28

1 authorities about the application of these laws.

2 D. HCSC Agrees Judicial Notice of Exhibits A, B, F, G, and J Are Appropriate.

3 HCSC not dispute that the Court should take judicial notice of some of the documents in
4 Mallinckrodt's RJN. HCSC agrees that the Court should take judicial notice of Exhibit J, *Humana Inc.*
5 *v. Mallinckrodt ARD LLC*, No. CV 19-06926 (C.D. Cal. Mar. 9, 2020). HCSC would point out,
6 however, that no factual findings from the Humana case would be applicable here, and the Humana
7 decision is no binding precedent. Courts have reached conflicting conclusions regarding the Humana
8 court's decision to dismiss, without prejudice, Plaintiff Humana's antitrust claims, and as explained in
9 HCSC's opposition brief HCSC's allegations differ in material respect to those that were considered in
10 the Humana decision, and the Humana court's approach to market definition is not widely accepted.

12 HCSC does not oppose the Court taking judicial notice of the Center for Drug Evaluation and
13 Research ("CDER") letter and labeling documents as executive department records. *See* Cal. Evid.
14 Code § 452(c); RJN Ex. F and G. To the extent that the Court takes notice of those documents,
15 HCSC requests that notice be limited to the existence of the documents and not the truth of the
16 contents. Similarly, Exhibits A & B are both documents appearing in the Federal Register and are
17 judicially noticeable. *See* Cal. Evid. Code § 451; RJN Exs. A and B. As explained above, however,
18 HCSC objects to the use of these documents to show that HCSC was on constructive notice of claims
19 against it. The Court can only notice the existence of the document and not their truth. *See Stockton*
20 *Citizens for Sensible Planning v. City of Stockton*, 210 Cal. App. 4th 1484, 1488 n.2 (2012) ("While courts
21 are permitted to take judicial notice of the existence of that decision and the factual findings contained
22 therein [citing Evid. Code, § 451(a)], they are not permitted to take judicial notice of the truth of such
23 findings").

26 **III. CONCLUSION**

27 For the reasons set forth above, Mallinckrodt's request for judicial notice should be denied in
28 part.

1 Dated: June 23, 2020

Respectfully submitted,

2 **SCHNEIDER WALLACE COTTRELL**
3 **KONECKY LLP**

4 /s/ Matthew S. Weiler

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[Additional counsel on signature page]

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiff,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and MALLINCKRODT
PLC,

Defendants.

Case No. RG20056354

**PLAINTIFF HEALTH CARE SERVICE
CORP.'S REQUEST FOR JUDICIAL
NOTICE IN SUPPORT OF
OPPOSITION TO DEFENDANTS
MALLINCKRODT ARD LLC AND
MALLINCKRODT PLC'S DEMURRER
AND MOTION TO STRIKE**

Judge: Hon. Stephen Kaus
Location: Dept. 19
Hearing: August 5, 2020; 3:00 p.m.
Complaint Filed: February 27, 2020

Trial Date: Not Set

REQUEST FOR JUDICIAL NOTICE

Plaintiff Health Care Services Corporation (“HCSC”) respectfully requests that the Court take judicial notice, pursuant to Cal. Evid. Code §§ 451-53, of the following documents in support of HCSC’s concurrently-filed Opposition to Defendant Mallinckrodt ARD LLC and Mallinckrodt plc’s Demurrer and Motion to Strike: (1) Order, *United States of America ex rel. Strunck*, No. 12-cv-0175 (E.D. Pa. Mar. 8, 2019), **RJN Exhibit 1**; (2) Complaint in intervention filed by the U.S. Department of Justice (“DOJ”) in *United States of America ex rel. Strunck*, No. 12-cv-0175 (E.D. Pa. June 4, 2019), **RJN Exhibit 2**; and (3) a press release by the U.S. DOJ, “United States Intervenes in False Claims Act Lawsuit Against Drug Maker Mallinckrodt Alleging Illegal Kickbacks,” June 5, 2019, available at <https://www.justice.gov/opa/pr/united-states-intervenes-false-claims-act-lawsuit-against-drug-maker-mallinckrodt-alleging> (last accessed, June 18, 2020), **RJN Exhibit 3**. The documents are attached as Exhibits 1 through 3 to the Declaration of Matthew S. Weiler.

BACKGROUND

HCSC alleges it was put on notice of antitrust-related claims by the publication of the FTC investigation in January of 2017. ¶ 175.

HCSC alleges that it put on notice of allegations of other wrongdoing, such as bribes paid to doctors and the scope and extent of the fraud related to the Chronic Disease Fund (“CDF”) by the actions taken by the U.S. DOJ in 2019. ¶¶ 178-180.

Mallinckrodt argues that HCSC’s claims are time-barred because they could have been discovered earlier through a number of sources including newspaper articles published in 2013. MPA at 23-24.

ARGUMENT

This Court may take judicial notice of “[r]ecords of (1) any court of this state or (2) any court of record of the United States or of any state of the United States.” Evid. Code § 452(d). Exhibits 1 & 2 are such court records noticeable under this rule because they are a court order issued by the United States District Court for the Eastern District of Pennsylvania, and a complaint filed in the same court by the U.S. DOJ. These documents are subject to mandatory judicial notice as (1) this filing serves

1 sufficient notice to Mallinckrodt and (2) the true and accurate copy attached provides sufficient
 2 information to the Court to satisfy Evidence Code § 453.

3 This Court may take judicial notice of “[o]fficial acts of the . . . executive . . . departments of
 4 the United States.” Evid. Code § 452(c). Exhibit 3 is such an executive record noticeable under this
 5 rule because it explains and announces action taken by the U.S. DOJ. *Licudine v. Cedars-Sinai Med. Ctr.*,
 6 3 Cal. App. 5th 881, 902 (2016) (“[W]e can take judicial notice of official acts and public records.”).¹
 7 Exhibit 2, which is the U.S. DOJ’s complaint in intervention, similarly reflects “official acts” of the
 8 United States. These acts are subject to mandatory judicial notice as (1) this filing serves as sufficient
 9 notice to the defendants in this action and (2) the true and accurate copies attached (and the internet
 10 addresses listed above) provide sufficient information to the Court to satisfy Evid. Code § 453.

11 Exhibits 1 through 3 should be judicially noticed because they provide the dates of publication
 12 of actions taken by the U.S. DOJ, including the filing of a complaint that publicly disclosed
 13 wrongdoing. The date of publication is relevant to refuting claims made by Mallinckrodt that HCSC’s
 14 claims are time-barred. *See Trinity Park, L.P. v. City of Sunnyvale*, 193 Cal. App. 4th 1014, 1045 (2011),
 15 disapproved on other grounds, *Sterling Park, L.P. v. City of Palo Alto*, 57 Cal. 4th 1193, 1210 (2013).
 16 Dates of documents reflecting acts such as issuing an order or filing a complaint may be judicially
 17 noticed under Section 452(c) of the Evidence Code. *See Cabill v. San Diego Gas & Elec. Co.*, 194 Cal.
 18 App. 4th 939, 950 (2011) (“we hereby grant Owners’ February 1, 2011, motion for judicial notice and
 19 take judicial notice of the certificate issued on January 27, 2011, by the Secretary of State.”).

20 The date that a *qui tam* complaint is unsealed or published can provide relevant dates for
 21 purposes of statute of limitations, even when Defendants argue that the wrongdoing should have
 22 been discovered earlier. *See Williams v. Countrywide Fin. Corp.*, No. 2:16-cv-04166-CAS (AGRx), 2017
 23 U.S. Dist. LEXIS 36495, at *21 (C.D. Cal. Mar. 13, 2017) (“As relevant here, plaintiffs allege that they
 24 first became aware that their appraisals were fraudulent on May 13, 2012, when the Lagow complaint
 25 alleging misconduct by LandSafe was first unsealed.”); *Int’l Union of Operating Eng’rs, Stationary Eng’rs*

26
 27 ¹ The comments by the Assembly Committee on Judiciary to Evid. Code § 452(c) note: “Under this
 28 provision, the California courts have taken judicial notice of a wide variety of administrative and
 executive acts, such as proceedings and reports”

1 *Local 39 Pension Tr. Fund v. Bank of N.Y. Mellon Corp.*, No. C 11-03620 WHA, 2012 U.S. Dist. LEXIS
 2 18281, at *21 (N.D. Cal. Feb. 14, 2012) (“Plaintiff pleads sufficient facts to establish equitable tolling
 3 of the statutes of limitation. Plaintiff alleges that it was unaware of defendants’ ‘deceptive practices’
 4 until the recent unsealing of several whistleblower complaints filed by defendants’ employees.
 5 Nothing in the FX rates reported to plaintiff indicated that the rates were false and included hidden
 6 and unauthorized markups or markdowns”).

7 CONCLUSION

8 HCSC seeks to establish the following facts:

9 The operative complaint in the *qui tam* action, *United States of America ex rel. Strunck*, was
 10 ordered unsealed on March 8, 2019. Exhibit 1.

11 The U.S. DOJ filed its own complaint in intervention on or about June 4, 2019 in the *Strunck*
 12 action. Exhibit 2.

13 The U.S. DOJ publicized the existence of the *qui tam* actions on June 5, 2019. Exhibit 3.

14
 15 Dated: June 23, 2020

Respectfully submitted,

16 **SCHNEIDER WALLACE COTTRELL**
 17 **KONECKY LLP**

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EXHIBIT 40

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Attorneys for Plaintiffs

SUPERIOR COURT OF THE STATE OF CALIFORNIA
IN AND FOR THE COUNTY OF ALAMEDA

HEALTH CARE SERVICE CORP.,

Plaintiffs,

v.

MALLINCKRODT ARD LLC (f/k/a
Mallinckrodt ARD Inc., f/k/a Questcor
Pharmaceuticals, Inc.), and
MALLINCKRODT PLC,

Defendant.

Case No. RG20056354

PROOF OF SERVICE

PROOF OF SERVICE

I, Tyler B. Smith, declare the following:

I am over the age of eighteen years and not a party to the within entitled action. I am employed at Schneider Wallace Cottrell Konecky LLP located at 2000 Powell Street, Suite 1400, Emeryville, CA 94608.

On **June 23, 2020**, I served the following document(s) described as:


- PLAINTIFF HEALTH CARE SERVICE CORP.'S OPPOSITION TO DEFENDANTS MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S DEMURRER AND MOTION TO STRIKE
- [PROPOSED] ORDER GRANTING PLAINTIFF HEALTH CARE SERVICE CORP.'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF OPPOSITION TO DEFENDANTS MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S DEMURRER AND MOTION TO STRIKE
- [PROPOSED] ORDER OVERRULING DEFENDANTS MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S DEMURRER
- DECLARATION OF MATTHEW S. WEILER [PROPOSED] ORDER OVERRULING DEFENDANTS MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S DEMURRER
- PLAINTIFF HEALTH CARE SERVICE CORP.'S REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF OPPOSITION TO DEFENDANTS MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S DEMURRER AND MOTION TO STRIKE
- [PROPOSED] ORDER DENYING DEFENDANTS MALLINCKRODT ARD LLC AND MALLINCKRODT PLC'S MOTION TO STRIKE
- PLAINTIFF HEALTH CARE SERVICE CORP.'S OPPOSITION TO REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF THE DEFENDANT MALLINCKRODT ENTITIES' DEMURRER AND MOTION TO STRIKE
- [PROPOSED] ORDER RE DEFENDANTS' REQUEST FOR JUDICIAL NOTICE IN SUPPORT OF THE DEFENDANT MALLINCKRODT ENTITIES' DEMURRER AND MOTION TO STRIKE

on the following interested party(s):

D. Eric Shapland
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1 [✓] **BY ELECTRONIC SERVICE** by electronically mailing a true and correct copy in PDF
2 format through SWCKW's electronic mail system to the email address(s) set forth above.

3 I declare under penalty of perjury under the laws of the State of California that the foregoing is
4 true and correct. Executed on June 23, 2020, at Emeryville, California.

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7 Tyler B. Smith